COSMETIC SURGERY PROCEDURES: QUESTIONABLE FRANCHISING OF CHEMICAL ACID PEELS—PART IV

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

WASHINGTON, DC, NOVEMBER 2, 1989

Printed for the use of the Committee on Small Business

Serial No. 101-71

U.S. GOVERNMENT PRINTING OFFICE

32-820=

WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

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COSMETIC SURGERY PROCEDURES: QUESTIONABLE FRANCHISING OF CHEMICAL ACID PEELS—PART IV

THURSDAY, NOVEMBER 2, 1989

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES AND ENERGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to call, at 10:25 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The Subcommittee on Regulation, Business Opportunities and Energy will come to order. Today, the Subcommittee on Regulation, Business Opportunities and Energy holds its fourth in a series of hearings on cosmetic surgery and procedures. The Chair notes the presence of a quorum.

Today, the subcommittee will be examining cosmetic surgery procedures which may be the fastest growing component of modern health care today, with unique impacts on patient safety, consumer protection, and competition between small care-delivery businesses. It is one of several areas of medical practice investigated by the subcommittee during the last 2 years to determine the effects of growth in new technologies, services, and marketing techniques, and their regulation, of the impact on patients and care givers.

These investigations are an important part of this subcommittee's efforts to exercise the oversight responsibilities conferred on it by the full committee pursuant to rule XI of the Rules of the Committee on Small Business. Rule XI directs the subcommittee to assess the impact of regulation on small businesses and to continually evaluate the need for corrective legislation in these areas.

Perhaps no trend in health care delivery is more pronounced than the phenomenon of doctors performing surgical procedures outside of the hospital setting. In the majority of instances, this phenomenon has resulted in high standard care at great savings for consumers. But as in every professional circumstance, while most practitioners appear to be skilled, ethical, and conscientious, unfortunately, there are many who are not.

The subcommittee has uncovered convincing evidence that in the multibillion dollar-per-year field of cosmetic surgery, some practitioners are improperly trained, operate in ill-equipped settings, and are hoodwinking patients through false or misleading advertising which promises more than can be delivered.

The subcommittee's information suggests that some individuals are extracting exorbitant profits at the expense of patients and of well-meaning physicians who have been lured into the cosmetic surgery field. Evidence indicates that highly sophisticated franchising operations are now in place which are rapidly spreading potentially dangerous practices across the country.

Although these operations may be some of the Nation's most lucrative small businesses, as of yet we don't know the extent of their profits or the volume of their sales. Although more and more citizens are directly affected by their actions, these businesses are unregulated. Their fast-moving interstate operations are beyond the effective control of State and local governments and, at present, nothing is being done at the Federal level to help the States protect their citizens from serious harm.

At a hearing in May, former Federal Trade Commission Chairman Daniel Oliver asserted that most cosmetic surgery advertising is a matter for local regulators. It's obvious to the Chair, however, that many cosmetic procedures, such as the one being examined today, chemical face peels, is a procedure that is being marketed interstate, from one end of the country to the other. It's equally obvious that deceptive ads and slick franchising schemes make it impossible for patients to make sound judgments in choosing doctors or procedures.

Aided and abetted by the sleeping watchdogs at the FTC, who in the Chair's view have abdicated their oversight responsibilities, a minority of practitioners have found their niche in the shadowy back alleys of medicine. These alleys are not patrolled by Government regulators, health care professionals, or insurance company auditors.

Nonetheless, cosmetic surgery procedures are in great demand. Our popular culture has sanctified the qualities of youth and beauty. Many will pay almost any price, and believe almost any sales pitch—especially from a doctor—for something that could make them look and feel younger. They offer the siren call of youth in a scalpel or bottle, guaranteeing results that are quick, easy, and painless.

Today, the subcommittee is going to evaluate one of the newly popular techniques known as the so-called nonsurgical face lift, or chemical peel. But what isn't new is the high-pressure sales tactics that are used to market these procedures to doctors and to patients alike. Now we have proof that pitches, that were formerly reserved for land schemes and selling blenders, have come to modern medicine.

At the subcommittee's May 31 hearing, Dr. Hugh Johnston, who is president of the Oregon Board of Medical Examiners, testified that—and I quote:

> The Oregon Board has recently revoked the license of a physician who was a franchise physican doing face peels. He killed an elderly lady whose post-operative care was entrusted to an untrained person in a local motel. There is a serious and widespread problem of routinely doing total face peels by someone who is untrained in an office setting. Despite the fact that this procedure literally cooks the skin, we can only function on a case-by-case basis. We have to sit idly by watching others of the same ilk until they damage a patient and we get a complaint, there is little we can do to prevent these tragedies.

Dr. Johnston explained that the cosmetic surgery field is riddled with false and deceptive advertising, but the State medical boards of Kansas and Oregon have told the subcommittee that State attorneys general routinely warn their medical boards to stay clear of these cases because they don't want to risk an FTC antitrust lawsuit.

For a constituent of mine, this was a prescription for disaster. Her doctor, a Gresham, OR, physician, had purchased a franchise for this procedure from a Florida marketing group—Medical Marketing Services, Inc. He and other doctor clients allegedly pay up to $50,000 for a kit of marketing materials, and several days of training by the company's doctor. The franchise company's written sales pitch says this is what he could get:

> An additional $100,000 to $400,000 can be added to your annual gross volume immediately when you're trained in our exclusive methods of endodermology.
>
> Medical Marketing Services, Inc., will teach the qualified doctor in just 1 week our safe, proven system. The exclusive system is responding to the ever-increasing demands of the 40-year-old who wants to look like she did in her twenties, the seasoned professional who needs that younger look to compete, and the wrinkled senior citizen seeking a newer, fresher look.

Our year-long investigation—particularly the testimony of medical board directors and doctors from virtually all specialties doing these procedures—suggests that at present the cosmetic surgery and procedures industry is riddled with false and deceptive advertising, contributing to genuine cosmetic carnage and generating high profits at the public's expense.

Early this year, the subcommittee uncovered a nationally advertised company offering franchised chemical peels, operating with apparent success from Fort Lauderdale, FL. A competing franchiser located in Wichita, KS, appears to be offering the same services. Further, it appears that some buyers of franchising operations later establish themselves as spin-offs, selling franchises through interstate advertising. Two of these spin-offs have been identified by the subcommittee so far. One is in West Palm Beach, FL, and the other in Landrum, NC.

Of equal concern to the subcommittee staff is the franchising operation of a LaJolla, CA, dermatologist. He, too, offers his unique formula, training and marketing, but at the going rate of an alleged $100,000.

But whether doctors are taking the pitch from Southern California, South Florida, Kansas, or North Carolina, they are taking the bait. Subcommittee staff has identified over 50 doctors who have allegedly purchased these marketing and training packages.

In June 1989, the subcommittee was forced to subpoena information from one of the first of these franchising operations in Fort Lauderdale, FL. This information is essential to the subcommittee's efforts to verify other information supplied to understand how these operations work, and to gauge the nature and extent of the problems they pose. The subpoenas followed the company's repeated refusals to supply even the most basic operating information.

Mr. Michael Walerstein, owner of Medical Marketing Services, Inc., Fort Lauderdale, FL, to date has refused to provide any but a token number of documents subpoenaed by the subcommittee. The subpoena was issued to compel Mr. Walerstein to provide market-

ing and training information that is critical to the subcommittee's analyses of these trends.

In the ensuing months, Mr. Walerstein has thwarted the service of subpoenas on him, has offered continuous legal bickering and vague objections to the subcommittee's subpoenas and, indeed, to the subcommittee's investigation itself. He has made 11th hour responses to virtually every request from the Chair, and to date, has produced only a handful of documents.

Thus far, without Mr. Walerstein's assistance, the subcommittee has been unable to find even one licensed physician who trains Mr. Walerstein's physician clients to do acid face feels. In fact, all three of Mr. Walerstein's known associates who have trained clients for him have been cited for practicing medicine without a license.

So-called Dr. Ronald Bennett, we have been informed, has been run out of both California and Florida for practicing without a medical license. Mr. John Gaul was a doctor whose license was revoked in Florida after he was found to be selling drugs to police posing as prostitutes.

Today, Mr. Walerstein, Mr. Bennett, and Mr. Gaul are under subpoena to appear before the subcommittee. We hope that at last we will receive answers to the most basic questions concerning this interstate marketing campaign.

But our concern about high-hype medical advertising goes well beyond cosmetic surgery and procedures. This is just one side show in a medical carnival of snake oil hustlers.

We will also hear testimony from two patients who had the chemical face peel allegedly performed by students of Mr. Walerstein, Mr. Bennett, and Mr. Gaul. Additionally, expert scientific and medical witnesses will testify on the inherent risks posed by these chemicals and procedures, particularly in the hands of the unqualified. Finally, the subcommittee has invited and certainly hopes to receive testimony from some 20 doctors who have allegedly purchased these acid peel packages.

[Mr. Wyden's statement may be found in the appendix.]

Chairman WYDEN. The Chair is particularly pleased to recognize Mr. Hancock, the gentleman from Missouri, who has been most helpful in going forward with the subcommittee's work for today's hearing. Mr. Hancock has a very busy schedule and we welcome your opening statement and your participation.

Mr. HANCOCK. Thank you, Mr. Chairman. I don't have a statement. In the interest of time, why don't we go on to the witnesses.

Chairman WYDEN. I want to thank the gentleman. Before we hear from our witnesses, I think it would be instructive for the subcommittee to see a portion of a franchise videotape designed to encourage doctors to buy the acid peel package. Dr. Frank Kutikek of Wichita, KS, sends this tape to interested physicians. His company appears to offer the same kind of marketing of training packages. This is a very brief tape. If the lights could be turned off, so the subcommittee can see the tape.

[Videotape presentation.]

Chairman WYDEN. Our first witnesses are Miss Brenda Ordoyne of Gretna, LS, and Miss Anne Deutsch of Fort Lauderdale, FL. We welcome both of you and thank you both for your cooperation.

It is the practice of our subcommittee to swear all the witnesses. Do either of you have any objection to being sworn as witnesses?

Ms. ORDOYNE. None whatsoever.

Ms. DEUTSCH. No.

Chairman WYDEN. Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. Miss Deutsch, why don't we begin with you. As I said, we very much appreciate your cooperation and welcome your statement.

TESTIMONY OF ANNE DEUTSCH, FORT LAUDERDALE, FL

Ms. DEUTSCH. Mr. Chairman, thank you for asking me to be here. If I appear to be a little nervous, believe me, I am.

I had a chemical face peel in March 1988, and my life has not been the same since. When I went in to have the acid peel done, I was a healthy 67-year-old who works with younger people, feels younger than my age, and wanted to look younger, too. In other words, I suffered a female ailment known as vanity.

But when I came out, I was nearly blind. After weeks of tests, excruciatingly painful tests, with needles put into my eyes to test the pressure and scalpels to scrape tissue from my eyes in order to determine the nature and extent of the damage, I was told the result.

I have permanent double vision, damaged corneas, and extreme sensitivity to glare that often makes it too painful for me to be outdoors in the sunlight and even to stand in the glare of any lights at night. I see all of you now double. None of you are the way I would see you if you were up close to me. I take steroids to try to control the inflammation in my eyes, but the steroids give me a much greater chance of developing glaucoma, which could leave me completely blind. I will require the care of an opthalmologist for the rest of my life.

This all happened to me because I was vain. It happened because I believed what a doctor told me. Dr. Wachtel had done surgry on my daughter 15 years ago, and he had done a good job, so I trusted him. It happened because Dr. Wachtel didn't know what he was doing. He decided to launch a new medical career well beyond his training in obstetrics and gynecology. But I felt I knew him and trusted him. It happened because I believed ads like the ones that say invitation to a younger face, and all of it without surgery.

Most importantly, I'm nearly blind today because people like me are at the mercy of the medical community. They won't stop a doctor from doing things that he is not qualified to do. They all seem to protect each other, not their patients. The Government just lets it happen. They let doctors decide what they are and are not qualified to do, where they can do it, and who they can do it to. They let these ads run all over the country, ads that confuse and mislead even the most skeptical people.

We all want to look younger, to feel better about ourselves. These ads tell us we can do just that, virtually without risk. According to the ads, these procedures are painless, and they're so safe they can be done in a doctor's office.

There is no way for any of us to find out whether we're told the truth or a lie. We don't know if the doctor is good or bad, if he's been well trained to do the procedure or not, or if he'll know what to do if complications come up. The system is failing us and we have no where to turn.

When I look back on how I got into this, I feel angry and taken. After seeing one of these ads, a friend of mine was curious and she asked me to go with her to one of Dr. Wachtel's seminar parties. We were supposed to learn all about nonsurgical facial rejuvenation that could erase wrinkles and years from the face.

The seminar seemed a lot like a Tupperware party: wine and cheese, slides, and even door prizes. The door prizes were discounts on chemical peels. There were also models who were supposedly satisfied patients of Dr. Wachtel's. For all I know, they may have been shills, though, given what happened to me.

There's not really much to tell about the actual procedure itself. I didn't know there was a problem at the time. I was in very little pain during my 8 days recuperating in the nursing home, and until 4 or 5 days after the acid peel, I thought everything was fine.

But when I got home, I realized immediately that my vision was very fuzzy. My little half-glasses, usually worn for reading, like most 60 year olds, did not help. I went back to Dr. Wachtel and he knew something was wrong and he sent me to a local opthalmologist. When he felt he was unable to treat my condition, he sent me to the Bascom-Palmer Eye Institute. The first thing the cornea specialist asked me was, "Why did you put croton oil on your face?"

In case you don't know, the acid peel that Dr. Wachtel uses is mainly phenol acid with a few drops of croton oil. The croton oil and the phenol interact, making the solution eat deeper into the skin.

I've learned to live with double vision, and I've learned to live with the fact that it's tough for me to do my job, tougher for me to drive and much tougher for me to get out at night at all. Knowing what I know now, I'm just glad to be alive and not completely blind.

If there is anything that I can do to warn other people about what can happen to them, I want to do it. I'm convinced that neither my Government nor the medical community is doing the proper job.

Thank you again for asking me to tell my story.

[Ms. Deutsch's statement may be found in the appendix.]

Chairman WYDEN. Miss Deutsch, thank you. We appreciate your speaking out, and you do it very forcefully and very well. We'll have some questions in just a moment.

Miss Ordoyne.

TESTIMONY OF BRENDA ORDOYNE, GRETNA, LA

Ms. ORDOYNE. Mr. Chairman, thank you for caring enough to try to protect me and others like me from doctors who don't know what they're doing and from others who don't seem to care what's happening to us. I am here today because I don't want anyone else to go through what my family and I did.

Four years ago this December I had a chemical face peel. I didn't have it done to make me look younger. I had it done to correct a scar on my right cheek. I've had the scar since I was 13, when a mole was removed to prevent it from becoming a melanoma. I had the acid face peel done by a doctor I respected, admired, and for whom I had worked for nearly 14 years.

Since I had worked for physicians for so many years, I thought I was a cautious and thoughtful patient. I thought I knew what questions to ask to protect myself, but I found out that I was wrong.

Dr. Andrew Hegre told me that the chemical peel was safe and easy—nothing but a piece of cake. But what I got was the most painful, frightening experience of my life. Today I have more scars than before the procedure. My eyes, my corneas specifically, are permanently damaged, leaving me with blurred vision, tremendous sensitivity to light, and more chances of developing cataracts, and ongoing doses of steroids and other drugs that themselves can cause serious side effects.

Looking back now, I don't know how I could have been so stupid. I not only feel stupid, but I'm very embarrassed to be here. I'm only here for one reason, and that's because I'm a citizen of the United States. Let me add that, please.

But I asked my doctor whether there could be complications. I asked him if I could be allergic to the chemicals, but Dr. Hegre said not at all. I even asked if there was any type of testing that could be done on my back or forearm to see if there was any type of reaction to that. He guaranteed me that there was no problem.

Even though I knew that Dr. Hegre had bought the chemical peel package because he was looking for a fast way to make more money, I had faith in him. Even though I knew he had only seen a couple of face peels done, and had only done eight or so himself, I had faith in him still.

I should explain that Dr. Hegre is an internist and allergist. He has an excellent reputation in the New Orleans area, and was thought of as being a brilliant diagnostician.

Despite everything that has happened—3 months of excruciating pain, fear that the open wounds all over my face would never heal, the threat of surgery on my eyes to correct the damage to my eyelids, and even the worry that I would never be emotionally or physically normal again—I still can't really blame Dr. Hegre. I believe that Dr. Hegre was just as surprised by what happened to me as I was. I don't think that he really knew what the complications could be. I don't think he knew how to watch for danger signs, and I don't think that he knew what to do about them once they actually showed up.

There are two types of burn victims. One is by fire and one is by chemical. Fire victims, fortunately, in some way—if you want to say they're fortunate—they are sent to a hospital immediately and they treat it as such. My chemical burn was a burn and I was not treated for over 2½ weeks as a burn victim.

I think that Dr. Hegre believed what he was told by Michael Walerstein, the man in Florida who sold him the chemical peel package, and by Ronald Bennett, who showed him supposedly how to do the face peel correctly. I think that Dr. Hegre really did believe that the peel was a quick, safe way to make money.

As the administrator in Dr. Hegre's office, I saw the material that that Mr. Walerstein sent him. I firmly believe that as long as advertising like this goes out to doctors, and then they pass it along to patients, more people will be hurt and more people will eventually be killed.

I would like to tell you briefly what happened to me from the time I first decided to have the acid peel done to the time when I began to find out just how many times things had gone wrong and how seriously I could have been hurt.

After Dr. Hegre came back from 3 or 4 days—really, it might have been a week—of watching Mr. Bennett perform several face peels in Florida, one on our receptionist, he did several patients who looked really quite good. I decided to ask him what the peel could do for my scar on my right cheek. It had never really bothered me, but after working with doctors for 14 years, they would look at me and say, "Oh, my gosh, let's do something to get rid of that scar on your face." So I proceeded to ask more questions about it.

So I said why don't you take care of it for me. I must confess that I was self-conscious about it. In fact, it was almost an obsession with me, after people kept continually looking at me, saying about the scar on my face.

I had never wanted to try to correct it because it didn't really bother me enough to have surgery. But the chemical peel was different, or so I was told. It wasn't really surgery with all of the attendant risks and complications; it didn't require general anesthetic; and I didn't have to go to a hospital to have it done. It seemed the perfect solution.

As I said earlier, I asked Dr. Hegre about the possible complications from the peel. He told me that no procedure was without risk, but that the peel was virtually foolproof. When I asked him about the possible risks from infection, he told me that he wouldn't even have to give me antibiotics after the procedure. When I asked him whether I might be allergic to the chemicals, he told me that there was no chance, since the acid removed only the first layer of skin and the chemical would stop reacting. Then to further support this, this powder that was applied to my face was an antibiotic powder in case something would come up.

In fact, Dr. Hegre told me the procedure was so easy and I would heal so quickly that in 6 days I would just look like I had been in the sun for 20 minutes. So I decided to have a chemical peel.

My son took me to the office the day of the procedure to see if. Excuse me, could I have some water?

Chairman WYDEN. There's some right there.

Ms. ORDOYNE. I'm sorry.

Chairman WYDEN. No, no. We appreciate your assistance. Take your time.

Ms. ORDOYNE. My son took me to the office the day the procedure was to be done. He was still in medical school at the time, and he later told me that he was horrified that the peel was done in nothing more than an examining room. There was no monitoring equipment, no crash cart, nothing.

One of the reasons that I had decided to go ahead with the peel was that I didn't have to have a general anesthetic. Dr. Hegre told

me that he would just give me something to take the edge off. But whatever it was he gave me, it knocked me out completely. I was not even semiconscious.

Dr. Hegre sent me home right after the chemical peel was done. I absolutely have no memory for the next 4 days. My son was constantly talking with the doctors at medical school and they said that God has a great way of doing a favor for a patient when they have such tremendous pain, as just an automatic click and it turns it off, which I did not have a memory for 4 days. I had amnesia, even though I could walk around.

My family tells me that I was delirious from the pain. Dr. Hegre had given my husband pain-killer injections of demorol, percocet and valium, to give me every 4 hours. But they didn't stop the pain. My family tells me that I was hysterical it hurt so much, that I said that my face felt like it was on fire. My daughter even put gloves at one time on my hands and taped the gloves to the sheet so that I couldn't try to take the tape off my face.

Over the next 48 hours, my husband repeatedly called Dr. Hegre. His only real advice was to try to keep her calm.

On the third day, Dr. Hegre came to the house, removed the tape. My family tells me that they are convinced he knew that something had gone wrong. Dr. Hegre had told me that the tape mask would easily come off, but here in the picture you can see, Mr. Chairman, that it didn't come off quite so well as the tape was supposed to.

Finally, on the fourth day, I began to realize what was going on around me. The pain had lessened a little, but by that time the itching was very terrible. But they were putting the antibiotic powder on at that time on me. When I looked into the mirror, I was horrified. I looked like a monster, with hideous scabs all over my face. I also realized for the first time that Dr. Hegre had put the acid on my eyelids, after I had told him not to.

When Dr. Hegre came to the house again on the sixth day—excuse me. There's an error in this. Dr. Hegre did not come that day. A nurse came to the house that day. She put a vasoline ointment on my face, which was supposedly to encourage the scabs just to come off. It was supposed to come off like a mask. It didn't. It didn't slough off at all. I could tell then that he was really—you see, that's an error. I'm sorry.

The mask didn't come off that particular day. It was the very next day when I called Dr. Hegre. He then allowed me to come to his clinic, to the house where he was having other ladies, the chemical peel being done. When he saw that the mask did not come off, then he proceeded to cut some of it off. The pain was awful then, because then what was left was just bare skin. It was very red and open and blistered.

Let me see if I can find where I can pick up here.

At no time during the entire period had he ever prescribed any antibiotic for me. Even I knew that an open wound, and particularly a burn, was very susceptible to infection. By that time, Dr. Hegre wasn't even prescribing pain killers for me. If you really want to know the truth, the doctor freaked out on me. At that point he left me. He left me without phone calls. I couldn't reach him for 4 or 5 days. He really, literally freaked out.

Like an opthalmologist told me, who knows Dr. Hegre very well, and she's very well known in the New Orleans area, she said, if I had done this to a patient, I would have jumped off the Greater New Orleans Bridge. I can understand that. But even so, I'm the one who had to go through this.

It was only then that a friend of my daughters came in from law school, and he was very frightened by what he had seen. He asked me when was the last time I had seen a doctor. At that point in time, I was—It's probably going to be hard for you to realize this, but I was so emotionally distorted, I mean, my IQ had to be at least 10. I mean, that's it, 10. I couldn't even think logically.

So immediately he went home to get his father, who was a doctor. He came to the house and immediately he got me to a dermatologist. But this was like 2½ weeks later, which was much too late. I shudder to think what would have happened if the doctor hadn't come to see me.

The dermatologist told me that the acid had eaten away four layers of my skin on my face. He immediately prescribed oral antibiotics and antibiotic ointment. Also, he advised me to be away from people for at least 2 to 3 weeks due to the risk of infection. I had open holes on the eyelids and under the eyes, which made it very susceptible to infection.

I began to see the dermatologist regularly, but even under his excellent care, my face stayed blistered for over 2 months and it way still raw for more than 3 months. Needless to say, the pain continued to be so severe throughout all those weeks. My face was so tender that it was agony just to walk in the house. The breeze hitting it was excruciating. Just touching it—I think if I had the opportunity to cry, which I wanted to so many times, and I couldn't even cry because the salt in my tears burned my face even more.

His concern over the damage to my eyes prompted the dermatologist to send me to an opthalmologist. I was scared to death when he told me that the acid, in his words, had burned three layers of my cornea. He went on to tell me that if one more layer had been burned, I would have been blind.

Also, I forgot to mention that if the acid had gone one more layer deep in the skin, it would have given me nerve and muscle damage and I would have been disfigured for life.

For weeks, I literally had holes in my eyelids and under my eyes. My eyelids were so damaged and swollen that they wouldn't close. For a while, the opthalmologist and the plastic surgeon I was seeing at the time thought that I would have to have corrective eye surgery to prevent the cornea from drawing out. I was very lucky, though, and my eyes finally healed.

I will never see normally again. Contacts can't correct my blurred vision, and I can't wear glasses any more because of the scar tissue around my nose. It irritates it. But I still can see. They have given me contacts now, one in one eye to see up close, and one in the other to see far. But it distorts the vision in the middle.

Today, I still see a dermatologist regularly because I get recurring cysts and inflammation due to the a lot of open pores. The only way to try to control them is to get steriod injections. But I worry about the long-term effects from these drugs. Nevertheless, I'm left with little choice.

When I look back on the last 4 years, I appreciate how far I have come. I remember that first Christmas. It was just 3 weeks after I had had the chemical peel, and I remember vividly that my family and I thought it was the best Christmas we had ever had, because we all knew at that time I was lucky to be alive, and it did look at that time that I would look normal again.

I remember, too, how I felt each time I had to put the ointment or peroxide on my face. I felt like I was touching a monster. You walk around the house, and a lady looks in the mirror many times during the day, brush your teeth, putting makeup on, and I had to treat my face 5 to 6 times a day with this special ointment. When you have a face looking back at you for 44 years and then you look in the mirror and see a monster and you touch the monster, emotionally—let me just say that, without God, and my rosary wrapped around my wrist, I don't know how I would have pulled through it, plus I had a good husband and a family to give me support. I really cringed to see how a lady or any other person, if they don't have the support of a family, or if they're not strong mentally, I don't know how they would pull through this emotionally. I know they would snap.

But I'm fortunate. I'm fortunate because I'm here, because I can see, and because I have a family that helped me through it. I'm stronger today because of this, and so is my family. But not one more person should have to go through this. Excuse me again.

Just one final note, Mr. Chairman. On top of everything else, Dr. Hegre tried to bill my insurance company for the chemical peel. What happened, he brought the insurance paper to my home and had my husband sign the paper before he had filled it out, which we thought—well, we really didn't know what to think at that time. We were all emotionally distraught. He had put that I had an impaired upper lid reflex and keratosis of the face. I had neither. But it is my understanding that these conditions are covered by my insurance, where cosmetic surgery or procedures are not. I think this form speaks for itself.

At that time I did call my insurance company, when I did find out that he did mail this in. Because being a patient of his, I was treated for insurance only for allergy reasons or general internist treatment. He treated my family. So I just thought this was normal. But I did call the insurance company and I told them please do not proceed any more claims on me, definitely not something that was done on December 6. I did not go on to tell them what because I was afraid of a lawsuit, to be perfectly honest.

Mr. Chairman, I want to thank you again for asking me to be here today. I hope that my testimony will help you make sure that patients are protected from untrained doctors who do more than they ask, or more that they should and can do safely. I think that the doctors and the patients are being tricked into believing that there is no risk from these cosmetic procedures. It is patients like myself and many less fortunate who pay the price, and the price is much too high.

Mr. Chairman, one thing I don't understand. The FDA goes through extensive research and studies even to pass Bayer asprin on the market. I'm not questioning you by any means, but why does the FDA not have any control over an acid peel or any type of

medication that's done in a doctor's office? That, plus—I know the money is a minority and all of that, and I didn't get any money out of this. Don't get me wrong.

But I own a business, and every year I have to submit to my landlord and to the State a copy of my insurance stating that I carry—I have to carry $2 million dollar coverage, where I'm located, because it's at a high risk and it's a large mall. Why aren't doctors asked to present this once a year to the Government or to their State representative? I think this is very important. Because sure, I have been paying medical bills for the past 4 years. Fortunately, I can afford it right now. But supposing this had made me blind, supposing I would have needed psychiatric help; who would have paid for these, whereas if the doctor had been covered by some type of malpractice insurance. Thank you, Mr. Chairman.

[Ms. Ordoyne's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, Miss Ordoyne. Your point at the end is what these hearings are all about.

To the best that I can ascertain, cosmetic surgery is the fastest growing area of modern health care, and it exists in a completely unregulated environment. In both of your instances, procedures were done in doctors' offices. If medical surgery is done in a hospital, that's one thing. There are significant protections in place, such as life support systems, and the opportunity for colleagues to review the work that's being done in a hospital. But this is an area of health care which I think is the fastest growing in America today, which exists completely outside of any oversight and accountability. That's why we're digging into the area.

Let me just ask a few questions of each of you. We are very appreciative of your speaking out. You were very blunt, Miss Ordoyne, about how this isn't a very comfortable experience to come and speak out. It is important that you know that we consider it essential to be able to hear first hand from people like yourselves, thereby building a factual record, so that the people of this country understand these problems.

I think you are aware that, from my opening statement, these are not abstract issues. As a Member of Congress from Oregon, in my own district, a woman was killed as a result of a chemical face peel. The Oregon Board of Medical Examiners today says that there isn't much they can do about it under current law. So we thank you both.

Let me ask you a couple of questions, if I might.

Miss Deutsch, you had some previous experience with the doctor you went to for the chemical peel. You said that you trusted him. It is my understanding that his professional expertise was in another area.

Ms. DEUTSCH. That's correct. He was and still is an gynecologist and an obstetrician. But in my mind, I assumed that possibly, after 20 years of doing this, he had burn out and was changing his specialty, which I did not think was so unusual. I did tease him, as a matter of fact, at the seminar, and asked him if he had both ends of us covered.

Chairman WYDEN. This is a matter of special importance to our subcommittee as well, because what we have come to be quite concerned about is essentially physicians practicing outside their field.

Ms. DEUTSCH. May I say that he is a board-certified physician.

Chairman WYDEN. In obstetrics and gynecology?

Ms. DEUTSCH. It doesn't say. It just says he's a board-certified physician. There is no way, when you call, that you can get any information about either a doctor or an attorney. You can call and they will tell you that yes, he is on our list, he's a member of our association. Does he have any malpractice suits? We don't know. We don't have that information. But that doctor can punch in a computer and he knows how many malpractice suits I have filed against other physicians. I don't have that same knowledge about the doctor, nor about the legal profession.

Chairman WYDEN. You can't get any real information. The yellow pages don't help you. If anything——

Ms. DEUTSCH. Not the kind of information you're looking for. As a matter of fact, the local opthalmologist that Dr. Wachtel sent me to is a member of the HMO that I am associated with, through the county that I work for. One of the girls in the office had told me that this particular doctor had several cases against him and that was the reason he was sending everybody to Bascomb-Palmer, because he didn't want to get involved any deeper.

I tried at that point—because I didn't know what was going to happen from that point on, whether this local opthalmologist was going to treat me or where I was going to go from that point on—I tried calling to find out information. I even called an ex-worker of mine who worked at the courthouse. The only information I was told was that I would have to go to the courthouse and go through every case that was ever filed against a doctor, which is ridiculous. I knew somebody who worked at the Broward County courthouse and I called her and asked her to research it, and she never called me back. So whichever road you go down, it becomes a dead end.

Chairman WYDEN. So we've established that this physician of long standing that you had is an obstetrician?

Ms. DEUTSCH. Yes.

Chairman WYDEN. How did it come about that he said that he was qualified to do face peels? You asked him and he said he had had some training of some sort or another?

Ms. DEUTSCH. No, no. He advertised locally, not under his name, but under the name University Facial Clinic, I think it is. He had a seminar at the organization that one of my friends belonged to, as I mentioned in my statement, and we decided to go down and see the seminar. At that time I discovered that it was Dr. Wachtel. I went over and I said is this the same Dr. Wachtel that was the obstetrician/gynecologist, and he said yes, but he wouldn't go into it any further.

He showed the slides, he showed the women that you saw on that page. Of course, he didn't go through what is presented to the doctors. But I saw slides. As a matter of fact, I met a neighbor of mine—which is the fact that decided me to use this doctor—who had had the procedure done, and she was fine.

Chairman WYDEN. Tell me a little bit, if you will, about these—I guess you could call them recruiting parties—and how these parties were used, in effect.

Ms. DEUTSCH. At organizations, they would go to temples, they would go to any organizations that women belonged to. They would

bring in a video camera. They would have models. They have sales consultants. I'm sure that they are sales consultants, because when you put your name on the list, they bother you quite a bit after that.

But I had made up my mind a long time ago that I was going to have something done. It wasn't difficult for him to get me. I knew I was going to have something done, and I knew I did not want to go under elective surgery. I did not want to go under a knife and I did not want to go in for a face lift. This was my alternative.

Chairman WYDEN. You said the program you were associated with was University Facial Medical Center?

Ms. DEUTSCH. Facial, right.

Chairman WYDEN. I have something they put out indicating that they bring door prizes and gift certificates——

Ms. DEUTSCH. That's exactly right, a few little door prizes. I don't recall what they were. But the gift certificates were toward the chemical peel.

The first time I called them, the first time the advertising was done, I called to get some information to find out how much the procedure would cost. They gave me a price, but they said if we use you as a model, we will take $1,000 off.

Chairman WYDEN. I'll have some additional questions in a moment, but I want to recognize my very patient colleague, the gentleman from Missouri.

Mr. HANCOCK. Thank you very much, Mr. Chairman.

My background has a little bit to do with the insurance industry. I used to be involved in it pretty extensively before I ended up in the U.S. Congress the first of the year. These procedures are considered cosmetic surgery and, normally, insurance companies do not pay for cosmetic surgery.

But I have an insurance claim form here that Mrs. Ordoyne signed. My question is, did your doctor indicate that there was some way there could be payment for this treatment through your insurance carrier?

Ms. ORDOYNE. He did try to submit it, but we called in—like I stated before, we did call the insurance company and tell them not to pay it, and they didn't.

Mr. HANCOCK. Was this discussed prior to the operation?

Ms. ORDOYNE. No; I always kept insurance forms in my folder. You see, I worked for the gentleman for 14 years, and I always kept signed forms, because they would send in insurance—two of my children and myself were under his care for allergies. We would see him for minor things, colds, et cetera, and my husband was seeing him for several things. So he would send in insurance forms on us. He would just let it go as insurance only because it was a benefit for us working with the clinic, which there was nothing wrong with that. Everything was always legit.

But then when I heard that he had submitted this, that's when I called my insurance company and told them definitely to not pay anything.

Mr. HANCOCK. But at the time you agreed to undergo this treatment, you did not anticipate at that time that the insurance company would be involved at all?

Ms. ORDOYNE. No, sir. You see, I was an employee and he was going to do me a favor.

Mr. HANCOCK. You mean he agreed to do this at no charge?

Ms. ORDOYNE. Right; because, you see, that's why I have the pictures. We were going to do it as a case history, to show all of the patients how easy a procedure it was. Then, when we saw what had gone wrong, then my cousin, who is an attorney, he did tell me, "Brenda, you've got to continue to take pictures."

Mr. HANCOCK. OK. Your husband is an attorney?

Ms. ORDOYNE. No, sir. My cousin.

Mr. HANCOCK. I beg your pardon. This would appear to be approaching an area of a little bit of an insurance fraud type of thing. Maybe that's a little blunt, but——

Ms. ORDOYNE. I'm sure. But I hope I don't get involved with anything like that because I've had enough. It didn't take that, so——

Mr. HANCOCK. But at the time, you were working for this doctor?

Ms. ORDOYNE. Yes; I was. I was the administrator for the clinic.

Mr. HANCOCK. How many other people had he treated with this?

Ms. ORDOYNE. With the chemical peel? Between 8 and 10, but he never did submit anything. I'm being honest.

Mr. HANCOCK. But you were familiar with the type of treatment and what the potential was—I read your testimony; I was not here as you were giving it. Do you feel like he talked you into this?

Ms. ORDOYNE. No; I have to be honest. He didn't. I was obsessed with the scar. I have to be honest. He did not talk me into it. He did the other patients, OK? Because they came to him, and the patients he did do, they had a lot of wrinkles. They did do it for a reason. Some ladies had, you know. liver blotches and all. I do have to say, they came out well. I was the unfortunate one.

No; he did not force me into doing it. That even makes me more stupid. But I did it on my own.

Mr. HANCOCK. I understand. Miss Deutsch, these meetings that you went to—and here again, I'm not making light of this at all—but I notice you said that you suffered a female ailment known as vanity. I think you'll find that that's probably a male ailment too.

Ms. DEUTSCH. I don't know that the men really understand that.

Mr. HANCOCK. All right. Is it primarily women that are going in for these treatments?

Ms. DEUTSCH. No; I think at this point men are going in for it, too. I don't know. A man can put a beard on his face and he doesn't have to worry about wrinkles. He's got an easy out.

Ms. ORDOYNE. I'll have to tell you, we did two men in the office.

Mr. HANCOCK. Is that right?

Ms. ORDOYNE. Yes; we did.

Mr. HANCOCK. It's an interesting thing that we're into here. There are all kinds of potential ramifications of what we're involved in. You could go into the doctor recognizing that cosmetic surgery is not covered under hospitalization insurance, and then all of a sudden it is covered, at least in the doctor's mind. It would appear to me that any doctor falsely submitting insurance claims should be prepared to face the consequences. Also, there ought to be some way they could find out if, in fact, a doctor carries malpractice insurance.

Ms. ORDOYNE. But can you imagine—excuse me.

Ms. DEUTSCH. The doctor that—Dr. Wachtel did have a sign in his office that he does not carry malpractice insurance.

Mr. HANCOCK. What exactly did the sign say?

Ms. DEUTSCH. That sign was very clear. But it is my understanding, in the State of Florida, they need to establish—it's either $200,000 or $250,000 fiscal responsibility. But they do not have to have malpractice insurance.

Mr. HANCOCK. Thank you.

Chairman WYDEN. I think my colleague has addressed a very important issue and we're going to follow this up and write a letter to the insurance commissioner as well, asking that this matter be inquired into. I think the questions my colleague has asked are very important ones and we ought to inquire further. Certainly, some serious questions have been raised on this insurance matter.

Let me ask you some additional questions, Miss Ordoyne. Let me tell you one of the things that concerns me the most about the story that you've recounted to the subcommittee. You're someone who has worked for a physican, as I understand it, for years and years and years—over a decade; is that correct?

Ms. ORDOYNE. Yes.

Chairman WYDEN. So you worked for this physician for over a decade. You had seen him work under a wide variety of conditions. Any way you slice it, you would be in a position to know vastly more about health care and procedures than most citizens in this country. My sense is, could most potential cosmetic surgery citizens ever be in a position to know as much about a physician as you?

Ms. ORDOYNE. No; that's why I said I feel so stupid. I mean, I asked all the right questions, I thought. I saw patients being done like this. The doctor who performed it, he was not only an internist, he was an allergist. So he was covered under those two things. Like an allergy, if something would happen, an internist, you know. Plus the doctors who he was affiliated with 2 years prior to that, and he had worked with them for about 10 to 12 years, they were dermatologists, and very good ones. So he was around dermatology. He even took courses in dermatology, so I really thought everything was covered. Plus, you know, the questions I had asked about the antibiotics, et cetera.

Chairman WYDEN. Now, you said that Dr. Hegre told you certain things to allay your fears. You said in response to my colleague that you were very interested in having this procedure done. This was not a question of someone coercing you but that you were interested in having it done, but that you had certain fears and concerns and that Dr. Hegre communicated to you in a variety of ways that you shouldn't be so fearful, trying to allay your fears.

Ms. ORDOYNE. Right.

Chairman WYDEN. What kinds of things exactly did Dr. Hegre tell you to try to allay your fears?

Ms. ORDOYNE. OK. I had asked, well, supposing it doesn't go—you know, if it goes past one layer of skin. That was my main concern, and that's why he proceeded to tell me it was explained to him, in which he thoroughly agreed upon, that it was like a permanent wave. After 20 minutes, the solution stops working, while this acid, after the first layer of skin, it can't react any more. It stops acting, so it can't go any deeper.

Then I asked him about the infection. I said you know people are allergic to different things. I'm allergic to grass and trees. He says don't worry about that because the powder is an antibiotic powder that we start applying after the second day and that would help anything there.

Like I said, I did witness quite a few patients before I did make my final decision. It was easy, very easy. The seventh day the ladies had a pink face, so they put on their makeup and walked out.

Chairman WYDEN. What you described to the subcommittee sounds just excruciatingly painful, painful beyond belief.

Ms. ORDOYNE. Right.

Chairman WYDEN. Did Dr. Hegre tell you, in effect, that this would not be very painful?

Ms. ORDOYNE. He said I would feel the first 4 to 5 hours a little discomfort but not pain.

Chairman WYDEN. It would not be keen? I'm sorry, I didn't hear.

Ms. ORDOYNE. The first 4 to 5 hours would be a little uncomfortable, but not severe pain, and that he would make sure to give me something to relieve that.

Chairman WYDEN. Certainly nothing was suggested that resembled the kind of agony that you were in.

Ms. ORDOYNE. None.

Chairman WYDEN. This business about your eyelids feeling like they had holes burned in them; nothing like that was ever suggested?

Ms. ORDOYNE. None whatsoever.

Chairman WYDEN. Is there any question in your mind that this physician was, in effect, practicing in a field where he didn't have adequate training?

Ms. ORDOYNE. Definitely, now. Now I think only a qualified dermatologist or plastic surgeon should be the only two physicians that should administer anything such as this.

Chairman WYDEN. This subcommittee feels that this is not a turf battle between one profession or another, but that this whole area lacks accountability and oversight and that's what we're trying to do. Your comments are helpful——

Ms. ORDOYNE. Mr. Chairman, a dermatologist and a plastic surgeon are, through their extensive years of intern and residencyship, they have the followup and the knowledge to treat patients with burns, et cetera, so they know how to treat a patient once complications may arise, whereas a regular physican would not be exposed to that type of problem.

Chairman WYDEN. Just one other question. With respect to these eye problems that you had, these very severe and painful eye problems, were any steps taken to try to protect your eyes in any way?

Ms. ORDOYNE. None whatsoever. In fact, I had asked not to have the chemical put on my eyelids because I was always squeamish with my eyes.

Chairman WYDEN. With respect to the staff that assisted on the procedures, was there an anesthesiologist or specialist in the room?

Ms. ORDOYNE. None whatsoever. My son was in the corner. He was a medical student, which was of no real help, really. His nurse

was a physical therapist—no, wait. A surgical tech. I'm sorry. She was a surgical tech.

Chairman WYDEN. You both have been very, very helpful. The picture you have painted is a frightening one. What you're basically saying is that what this field is really all about is trying to find warm bodies and valid credit cards and get them in the door.

Ms. DEUTSCH. That's true.

Chairman WYDEN. Run up the cash register. That's not my view of what modern health care is supposed to be about. You all have really built a very, very strong case and argument for the kinds of substantial changes that I think are necessary. So we thank you. We're going to want to be in touch with you in the days ahead. But I know this morning can't be a lot of fun, having to speak about personal things like this. We really appreciate and admire you're being willing to speak out.

Ms. ORDOYNE. Thank you.

Chairman WYDEN. Thank you both, and we'll excuse you at this time.

Chairman WYDEN. Our next panel is scientific and medical experts. Representing the American Academy of Dermatology is Dr. Thomas Jansen, a dermatologist from Little Rock, AR, and Dr. Harold Brody, a dermatologist from Atlanta, GA. Also, Dr. Mark Montgomery, professor of toxicology, University of South Florida at Tampa, FL. If you three will come forward.

Dr. JANSEN. Mr. Chairman——

Chairman WYDEN. Excuse me one moment, Dr. Jansen. We have some formalities that we have to go through and then we're anxious to hear from all of you.

It is the practice of the subcommittee regulations to swear all the witnesses that we have before our panel. Do any of you have any objection to being sworn as a witness today? Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. Gentlemen, we thank you very much for the cooperation and the assistance that you have afforded the subcommittee. Is it your intention that each one of you would make a statement, or will one speak for the academy? What are your desires?

Dr. JANSEN. I will speak for the academy, and Dr. Brody is the source person for questions later on.

Chairman WYDEN. Very good.

Dr. JANSEN. I believe that Dr. Montgomery, who is not representing the academy, has a statement to make.

Mr. MONTGOMERY. Yes, sir, I do.

Chairman WYDEN. All right. Let us then begin with you, Dr. Jansen. We are going to make your prepared remarks a part of the record in their entirety. The Chair does not want to cut anyone off, but to the extent that you could hit the principal concerns you have, all your prepared material will be made a part of the formal record.

So, Dr. Jansen, why don't we just begin with you, and again, we appreciate your cooperation.

TESTIMONY OF THOMAS JANSEN, M.D., PAST PRESIDENT, AMERICAN ACADEMY OF DERMATOLOGY, LITTLE ROCK, AR; ACCOMPANIED BY HAROLD BRODY, M.D., ATLANTA, GA

Dr. JANSEN. I am Thomas Jansen. I am former chairman of the Department of Dermatology at the University of Arkansas; immediate past president of the American Academy of Dermatology; and a practicing board-certified dermatologist from Little Rock, AR. Accompanying me today is Dr. Harold Brody, who is board-certified in dermatology in private practice in Atlanta, GA, and a leading authority on chemical face peels. Dr. Brody has been active in teaching at Emory University and is a member of the American Academy of Dermatology, and of the board of directors of the American Society for Dermatologic Surgery.

The American Academy of Dermatology is a national medical specialty society representing more than 8,000 practicing physicians of dermatology. The American Society of Dermatologic Surgery represents approximately 2,000 dermatologists who specialize in the diagnosis and surgical treatment of diseases of the skin.

We commend you, Mr. Wyden, and the subcommittee for your review of cosmetic surgery. As the popularity of safe, effective cosmetic surgery increases, it is important to ensure that patients are not misled and that they are educated concerning the advantages and disadvantages of these procedures. Furthermore, it is paramount that physicians be appropriately trained to offer these services.

The academy testified before this panel on April 4 of this year—and I was pleased to be here at that time—and at that time we went into a discussion of the qualifications of dermatologists, their training, et cetera, and I will not repeat it now. We will, therefore, limit our comments to the specific issue under discussion this morning, that if facial chemical peels. Dr. Brody and I will then be pleased to answer any questions that you have.

Chemical peeling, or chemexfoliation, is a relatively common dermatologic procedure. It consists of the application of a chemical agent that destroys superficial layers of the skin, resulting in peeling of those layers.

The benefits of chemical peeling are many. Increased feelings of self-esteem and self-worth are important among them. The procedure's increasing popularity and acceptance indicates that patients often consider the benefits greater than the risks involved, which are minimal if the procedure is properly performed by a well-trained physician.

It is widely believed that the use of chemical peels to improve the condition and appearance of the skin goes back to ancient times. Dermatologists have been pioneers in modern chemexfoliation since the turn of the century. Since that time, substantial progress has been made in understanding both the nature of the skin and the variations of treatment under discussion this morning.

Most people think of skin peeling as a way to rejuvenate the skin only, and indeed, that is one of its uses. However, it is also an effective treatment for removal of a number of skin abnormalities and it is increasingly believed that skin peels may prevent the develop-

ment of skin cancer. Precancerous growths and probably early cancerous growths are destroyed in the peeling process.

Facial peels are divided into three main categories: The superficial peels, which consists of the application of mild acids or chemicals to treat problems such as pigmentary changes, fine wrinkling, or scarring. Often used is a low concentration of trichloracetic acid or another member of this acid group.

Light peeling is generally safe, effective, and inexpensive. It produces excellent results and enjoys wide patient acceptance. There are usually no significant complications.

Medium depth peels are commonly used for photoaged skin, warts, and wrinkles. They will usually produce improved results over superficial or light peels but do not expose the patient to the increased risk of complications associated with deeper phenol peels.

Deep facial peels, usually performed with the more toxic chemical phenol, are used for more severe abnormalities. They are much more extensive in their procedure and require thorough patient screening and evaluation and extensive training on the part of the physician performing that procedure.

Deep phenol full facial peels can cause more severe complications and side effects, such as pigmentary and textural changes, scarring, infection, erythema or redness of the skin that persists, atrophy or thinning of the skin, and, most importantly, cardiac or kidney problems.

Proper patient screening and selection therefore is imperative. Physicians should be careful in recommending the procedure to patients with so-called skin types IV to VI—that is, dark skin, olive skin, brown or black skin. Darker skinned individuals experience a higher percentage of complications and often require a longer period of time for the skin to return to normal.

Other contraindications include a history of herpes simplex, previous keloid or scar formation, and a history of cardiac disease. People on certain medications or who have taken accutane, a drug to treat acne vulgaris, or photosensitizing drugs, should not undergo the procedure until an appropriate amount of time has lapsed since those medications were given. Individuals with kidney problems should probably avoid phenol peels because of the possibility of renal toxicity.

Only patients with a thorough understanding of the procedure, its risks and benefits, and its possible side effects, and who have realistic—should provide the patient with realistic expectations.

Chemical face peels, especially deep full face peels, should only be performed by physicians with extensive knowledge, training, and experience in skin types, the care of the normal skin, and the diagnosis and care of diseases of the skin and adjacent tissues.

Most chemical face peels are performed by dermatologists, plastic and facial plastic surgeons and otolaryngologists who are thoroughly trained in the procedure and its possible complications and treatment of those complications, and who can provide extensive pre- and post-peel treatment and patient evaluation and follow-up care. This is a medical treatment and not a procedure to be performed by lay people, such as aestheticians and cosmetologists, or by inadequately or poorly trained physicians.

You asked that we address in our testimony the issue of exodermology and the marketing of chemical face peels.

In 1987, the American Academy of Dermatology petitioned the Federal Trade Commission to investigate organizations known as the World Health Exodermology Center, the Medical Marketing Services, Inc., and the Perma-Derm Academy. Our concerns were many, and I will highlight a few of those concerns.

Exodermology is a coined term with no meaning in the medical lexicon. Brochures from the World Health Exodermology Center have claimed that exodermology is a recognized AMA specialty. It is not. From what we have learned, exodermology is a term used to describe a full phenol facial peel.

The academy is extremely concerned that in addition to false claims of medical legitimacy, World Health Exodermology Center promotional materials minimize the substantial risks associated with this delicate and potentially dangerous procedure. It should be performed only by thoroughly trained physicians.

Medical Marketing Services, which appears to be affiliated with the World Health Exodermology Center, aggressively markets endodermology, yet another fictional name with no meaning in the medical lexicon. Its promotional materials, in addition to minimizing risks, claim individuals can learn a safe method of facial peels in just 1 week. This is simply not possible and has the potential for putting many individuals at risk of serious and disfiguring injury. Dermatology residents, for example, spend 3 years in training at a minimum to learn the structure and function of the skin and the various skills necessary to perform dermatologic surgical procedures.

Patients may not be warned of all the potential complications of these peels, are lulled into a false sense of security, and are subjected to the multiple toxicities of the chemical phenol, which can induce heart irregularities and complications such as those listed.

Finally, the academy's complaint to the Federal Trade Commission addressed the Perma-Derm Academy which purports to license and certify dermologists. Again, dermologist is a coined term and designed, in our opinion, to create the impression that its graduates, who are called board-certified dermologists, are not medical doctors, and that has led to a great deal of confusion not only in the lay press but the medical press as well.

In conclusion, these are the points we would like to underscore: Chemical face peels are a legitimate medical procedure with significant risks as well as benefits; there is no one chemical or chemical mixture or technique appropriate for every patient; there are patients with certain conditions who are inappropriate candidates for the procedure; lay people or inadequately trained physicians should not perform chemical face peels; and patients should be fully informed as to the risks of possible complications and have realistic expectations before undergoing the peel.

Mr. Chairman, Dr. Brody and I would be pleased to answer any questions.

[Dr. Jansen's statement may be found in the appendix.]

Chairman WYDEN. Doctor, we thank you and we thank you for your cooperation. We welcome you back again and appreciated your cooperation before and today as well, for both of you.

Dr. Montgomery, we will make your prepared remarks a part of the record. If you, too, could highlight some of your principal concerns. I know there's almost a biological compulsion to read a statement that you've spent considerable time on. We will put it all in the record. If you could just highlight your principal concerns for us, it would be very helpful.

TESTIMONY OF MARK MONTGOMERY, M.D., PROFESSOR OF TOXICOLOGY, UNIVERSITY OF SOUTH FLORIDA'S COLLEGE OF HEALTH, TAMPA, FL

Mr. MONTGOMERY. Yes, sir. Thank you, Mr. Chairman, members of the subcommittee, staff and interested parties. I do, indeed, welcome the opportunity to speak before you. I hope that my comments and answers to your questions will be helpful.

My name is Mark Montgomery. I am a toxicologist, currently employed as the director of the toxicology laboratory at the VA Hospital in Tampa, FL. I am also a full professor of toxicology at the University of South Florida's College of Public Health, also in Tampa, sir.

Since graduating from Johns Hopkins with a Ph.D. in biochemical toxicology back in 1972, I have taught toxicology at several U.S. universities. During that time, I have taught virtually all aspects of phamacology, which just for clarity is the beneficial and toxicological aspects of prescription drugs, and also toxicology, which is the specialty that deals really with adverse effects, not only of prescription and nonprescription pharamceuticals but also chemicals in general.

I have taught these topics to medical students, dental students, pharmacy students, nursing students, graduate students working on research degrees, and various hospital staff, more students over the years than, unfortunately, I can even remember. Also, I do serve on the editorial board of the Journal of Toxicology and Environmental Health.

Mr. Chairman, I do also routinely provide expert opinion to the Florida Department of Professional Regulation, on those matters before that board concerning the mispractice and perhaps malpractice of licensed physicians. I also assist the Florida Department of Labor and the Florida Department of Criminal Investigation in certain matters.

In all of these cases, I appear as a trained toxicologist with perhaps approximately 20 years of experience, not as a Government witness, and it is in that capacity that I do appear before you today, sir.

On October 24, you wrote to me about your concern about unqualified doctors and, in fact, lay people who are performing medical procedures for which they may have little or, indeed, no training on. It appears that in some of these instances perhaps greed has replaced sound and proper medical judgment. Certainly as a South Floridian, I do share this subcommittee's concern over the rampant growth of this deceptive medical advertising and practices. I have seen, unfortunately, many of these in South Florida. We may be ripe down there for a number of reasons that may, in fact, be obvious.

Specifically, sir, you asked me to provide to the subcommittee my expert opinion on the toxicity of two chemicals—phenol and a chemical called trichloroacetic acid, which if it is adequate, I will just refer to as TCA.

I believe—and I do not mean this to sound too dramatic, sir, but in fact I do believe it—that both of these chemicals used in chemical face peels in the hands of untrained doctors and lay people is equivalent to the same situation of allowing drunks on the highway. You can get away with it every now and then, but if you do it a lot, sooner or later it's going to cause you extreme pain and you may, in fact, hurt other people.

Phenol, which is also known as carbolic acid, is an extremely toxic, corrosive chemical that will, in fact, dissolve protein. That's what we use it for in the laboratory, sir, to dissolve protein. It will also do that to human skin. As a result of this property and, hence, toxicity, it is standard laboratory practice, whenever anyone uses this solution or combinations of phenolic solutions, to wear protective gloves and a protective face mask.

In my opinion, the application of phenolic solutions places the recipient at a high degree of risk for the development of mild to severe chemical burns. These burns may indeed lead to a number of toxic results, as you've heard described to you today, including extreme pain at the site of application, permanent discoloration, and, in fact, irreversible scarring. Additionally, the denuded areas of skin will be highly susceptible to opportunistic infections due to the removal of these outer barrier layers of skin that are normally there.

Also, since this chemical is being applied to the face, it must be emphasized that the eyes are highly vulnerable to chemical burn simply due to the lack of an obvious protective barrier. Any small degree of splashing or or inadvertent application to the surface of the eye would lead to immediate excruciating pain and with a final result of partial to, indeed, complete blindness.

Now, regarding the second chemical, the trichloroacetic acid, or TCA, virtually all of these previous comments are applicable. This is a very strong, penetrating acid that is used routinely in my laboratory and many, many others to precipitate or actually coagulate proteins. It must be handled with extreme care and will cause severe pain and, again, chemical burning upon dermal application.

From a toxicological point of view, sir, it is very difficult for me to imagine any amount of phenol or TCA, even diluted, being applied to the human face. The resulting burns could be devastating and the possibility of infection is tremendous. A mere drop of these materials in the eye, as I mentioned, could lead to severe occular problems.

Mr. Chairman, please understand, I am not a plastic surgeon; I am not a dermatologist. I can perhaps imagine for you a very limited and specific situation where, in the hands of a highly trained specialist, using proper antiseptic precautions, on a proper skin type, with comprehensive follow-up care, there may be a role for these materials. But, sir, aside from these very limited possible applications, again in the hands of a highly skilled specialist, I cannot imagine a role for these toxic chemicals in human dermatology. In the hands of other doctors and, my goodness, sir, in the hands of

lay people, the use of these chemicals is barbaric and, as you know, may be lethal.

Thank you very much for the opportunity to present this opinion, and I will try to answer any questions.

[Dr. Montgomery's statement may be found in the appendix.]

Chairman WYDEN. Doctor, thank you very much.

Dr. Brody, you have no prepared statement you want to give, is that correct?

Dr. BRODY. That is correct.

Chairman WYDEN. Let me see if I can get a few basics out on the table. What these national franchisers are marketing is exodermology and endodermology. Is there any medical distinction between the two of these procedures, either Dr. Jansen or Dr. Brody.

Dr. JANSEN. None that I'm aware of.

Mr. MONTGOMERY. I don't have the slightest idea, sir. It's just two words.

Chairman WYDEN. Dr. Brody, any difference that you know of between these two procedures that are being marketed by the national franchisers?

Dr. BRODY. No, sir, and they are not medical terms at all. They are concocted terms.

Chairman WYDEN. Now, exodermology is advertised as a nonsurgical procedure or face lift. Gentlemen, is this an accurate description? Dr. Jansen?

Dr. JANSEN. The term surgery has a much broader use than cold steel surgery alone. Most people think of surgery as using a scalpel to remove something or to do a procedure. But we also speak of cryosurgery, which is a freezing procedure. We speak of laser surgery, in which you have a resolution of lesions in the skin with a laser beam.

There are some people who refer to this as a form of chemo-surgery or chemical surgery. So just because the term surgery is not used in the promotion or advertising by this firm doesn't lessen my feeling that the depth of destruction is a form of chemical surgery.

Chairman WYDEN. Dr. Brody, through exodermology or endodermology, would there be a wound that would be equivalent to a scalpel incision?

Dr. BRODY. Yes; certainly there would. But one would have to clarify that this is not a face lift at all. Chemical peeling is used for sun damage, to improve the quality of the skin. If you look at that skin after all the swelling has disappeared, all of the creases and folds and furrows, not wrinkles, but the larger defects are still going to be present and they are still corrected by the standard face lift. So to say this is a nonsurgical face lift is completely erroneous, because it is a surgical procedure and it is not a face lift. It is a quality of skin improvement.

Chairman WYDEN. Do you believe—I'll ask you, Dr. Montgomery—that it's possible to learn the appropriate medical uses of phenol and TCA in the course of a training session that lasts a few days or a week?

Mr. MONTGOMERY. Sir, I've been in the business of dealing with toxic chemicals for 20 years, and particularly with trichlorocetic acid, and to answer your question, no, sir. It is not a simple chemical, and neither is phenol. Certainly to give it to a person who's

going to be swabbing it on one of the most sensitive areas of the human body, with the proximity of the eyes being millimeters away, no, sir.

Chairman WYDEN. Should a laymen be allowed to train medical professionals to use and apply these kinds of substances to the body?

Mr. MONTGOMERY. My goodness, no.

Chairman WYDEN. Would you agree, Dr. Montgomery, with the assertion that the kinds of advertisements you've seen, the ones that are being marketed around the country, understate the risks and the dangers that are inherent in these chemical peel procedures?

Mr. MONTGOMERY. No pun intended, that is an understatement, sir. That is—if they ever told the people the inherent dangers, there would not be a business. It's that simple.

Chairman WYDEN. Do these chemical burns, gentlemen, differ in any significant way from the kind of burn a person would get who was exposed to a fire?

Dr. BRODY. Generally, the burns from a fire extend down to the fat, if you're talking about a third degree burn. But these are controlled burns, controlled wounding, and there is a great deal of work on phenol and trichloroacetic acid in various strengths to understand what to apply based on the defects that the patient has on the face. The difference is basically that you can control that if you understand the mechanisms of the chemicals and the face. But in a fire, it could be at any depth.

Chairman WYDEN. Even a very diluted form of phenol or TCA would pose a great threat to the eye, would it not, Dr. Montgomery?

Mr. MONTGOMERY. In my opinion, yes, sir, absolutely.

Chairman WYDEN. Are the kinds of problems that our two previous witnesses described—I think three were here—representative of the kind of risks to the eye that one would see with untrained individuals practicing these procedures?

Mr. MONTGOMERY. No, sir. I think these two ladies were lucky. They still have partial vision.

Chairman WYDEN. Your view is it could have been significantly worse, given the risk to the eye, with untrained people applying this diluted form of phenol and TCA?

Dr. BRODY. The eye is so sensitive that one takes particular care when applying the solution around the eye, but most people do not apply tape around the eye area for this particular reason. The solution can run out from under the tape or be applied too heavily if not properly understood. So the majority of people leave the tape off around the eyes because this does increase further the penetration of phenol.

Dr. JANSEN. I would like to make one comment. Very dilute phenol preparations, indeed, are available over the counter. You can buy calamine lotion with carbolic acid or phenol, or vasoline that's carbolated vasoline. It is not uncommon for over-the-counter products or for preparations made upon the request of a dermatologist to include a quarter or half a percent phenol because of its effect to relieve itching. It has an effect on the nerve fibers in the

skin to relieve itching. So the indictment is one more of strength and not against phenol completely.

Chairman WYDEN. We have been looking at the matter of untrained physicians performing these procedures, but I'm not aware of any controls over others who might be in a physician's office in terms of applying procedures. Is there any regulation that would restrict a physician from employing someone to do the peels in the same way that a dental hygienist cleans teeth or a physician's assistant might give an injection?

Mr. MONTGOMERY. I'm not a physician, sir. I'm a scientist. I really don't think I could answer that.

Dr. JANSEN. I'm not sure I completely understood the question. But I have another physician in my office——

Chairman WYDEN. No; I'm inquiring whether there are restrictions on say, an assistant applying these——

Dr. JANSEN. The restrictions on medical aides or assistants or physician extenders under direct control of a physician varies greatly from State to State. I'm not aware that in the State of Arkansas there is any such constraint by law.

Chairman WYDEN. I'm not aware of any constraints anywhere by law on assistants to those performing these procedures being restricted; are you gentlemen?

Dr. JANSEN. No.

Dr. BRODY. They would operate under the umbrella of the physician that had hired them.

Chairman WYDEN. What I'm concerned about is that we're having enough problems already, based on these two panels, with untrained physicians. I know of no controls on assistants to the physicians as well. I'll hold the record open on this poin. If you would like to add anything to it please do, but I don't know of any restrictions on assistants whatsoever.

Dr. JANSEN. Our academy staff made a partial research on a related subject, and I don't believe that anything was found by our staff in Evanston.

Chairman WYDEN. Are you aware of any States which allow cosmetologists to perform chemical face peels, gentlemen?

Dr. BRODY. In the State laws regarding the practice of medicine, I'm not aware of any States that have any regulation saying that it cannot be done. In other words, it is omitted. Therefore, one might infer that a cosmetologist could do a procedure such as this because there's just no reference to it.

Chairman WYDEN. Doesn't California have a law which prohibits cosmetologists——

Dr. BRODY. This morning I was told something to that effect, but I have no knowledge of that.

Dr. JANSEN. I saw the statement about the 10 percent limit as well, that apparently it limits it to 10 percent or less. But that is new knowledge to me.

I would make the plea that you can take a 10 percent solution, apply it, permit it to dry and reapply it, and that the total volume of substance on the skin that could be absorbed or produce the changes we're looking at would be as great as the stronger preparations. So if that is a law in California, I would think it would not be a very good law to have on the books.

Dr. BRODY. Yes.

Chairman WYDEN. Is this becoming a particularly lucrative area of medical practice, in your opinion?

Mr. MONTGOMERY. In the State of Florida it is, sir.

Chairman WYDEN. Dr. Jansen, Dr. Brody?

Dr. JANSEN. I think we're aware that cosmetic procedures have become more and more common and that, indeed, is why we're here this morning, because more and more people are requesting those things of physicians.

Chairman WYDEN. But this particular procedure or process, the endodermology——

Dr. JANSEN. It's been done for a long, long time. In fact, lay people were doing it in New York in the twenties and thirties. Some of the so-called best technicians in this procedure at one time were people who brought the techniques and their formulas from Europe. So it has been done for a long time. I think it's receiving more publicity and I think it's part of the advertising attitudes that medicine can now embrace that which leads toward the more common knowledge of the procedure.

Chairman WYDEN. One last question. Is it your sense that many people see this procedure as, in effect, rejuvenating the skin when, in fact, what it is really doing is burning away skin? Is that something that——

Dr. JANSEN. The burning rejuvenates. It is rejuvenating the skin. You can show by microscopic control that the tissue beneath the outer layers of the skin are more youthful, are rejuvenated. So although it's a controlled destructive procedure, there are many other things that we use even surgically, like dermabrasion, that rejuvenate the skin. So it does rejuvenate as well as burn the skin.

Chairman WYDEN. You all have been very helpful. We appreciate the ongoing cooperation that you have shown the subcommittee.

We are going to take a 15 minute break at this point and reconvene at about 12:20. All three of you will be excused at this time.

The subcommittee stands in recess until 12:20.

Chairman WYDEN. The subcommittee will come back to order. The Chair is sorry for the inconvenience for all concerned. There is a great deal going on on the floor.

Our next witness will be Mr. Michael Walerstein, president and owner of Medical Marketing Services, Inc., Plantation, FL; Mr. John Gaul, Atlanta, GA; and Mr. Ronald Bennett, Beverly Hills, CA. Will all three of you gentlemen come forward. If you desire to have counsel with you today, please come forward.

Mr. BARMAK. Mr. Chairman, my name is David Barmak. I represent Mr. Walerstein.

We have, as we informed your staff director during the recess, invoked and would request that you apply the rule of this subcommittee and of the House which would require that radio and TV coverage cease during the period of this hearing involving Mr. Walerstein; that is, that still and television photography lenses be covered and that any radio devices or tape recordings be turned off.

Chairman WYDEN. Mr. Barmak, I understand you represent Mr. Walerstein. Mr. Walerstein must come forward in order to make that application. The Chair is informed that he has an application to make and we must have him come forward and swear him in,

and as soon as that's done, we will proceed directly to this application.

Mr. BARMAK. With all due respect, Mr. Chairman, he is prepared to do that, provided that the photography equipment is turned off. The rule provides:

> No witness served with a subpoena by the committee shall be required against his or her will to be photographed at any hearing or to give evidence or testimony while the broadcasting of that hearing by radio or television is being conducted.

He does not intend to be photographed. He has a right, under your rules, to require that the equipment be turned off. With all due respect, sir, I suggest that my request to you, that you accommodate his request, is appropriate under your own rules.

Chairman WYDEN. I'm advised by the counsel of the House that, based on the precedence of the House, the application must be made at the time he is sworn in. Your client will not come forward to be sworn in at this time?

Mr. BARMAK. Not if he's to be photographed. The rules require that he not be required against his will to come forward and be photographed. That is our interpretation of the plain English meaning of that rule.

Chairman WYDEN. Your desire is to make the application at this point and then your client would come forward and answer the questions of the subcommittee?

Mr. BARMAK. Yes; he is here to testify today and to answer all appropriate questions and fully intends to do so. He is prepared to do so. But he intends to have the benefit of the rule that I have referred to.

Chairman WYDEN. Let us have the cameras be turned off at this time. Let the record show that this is at the request of Mr. Walerstein's counsel. The relevant rule in this regard is rule XI, and the cameras will be turned off at this time at the request of Mr. Barmak, counsel for Mr. Walerstein. This is a rule of the House and this subcommittee is particularly concerned that all witnesses before the subcommittee be afforded all their procedural rights. So at the request of Mr. Barmak, the cameras will be turned to the ground.

Mr. BARMAK. Thank you, Mr. Chairman. Do I understand as well that, in accordance with that same rule, that all microphones used for coverage will be turned off?

Chairman WYDEN. That is the House rule, and the Chair directs that that rule be complied with and that those microphones be turned off.

Let the record also reflect that the subcommittee staff has handed to Mr. Barmak a copy of the rules of the subcommittee and the House for their use and their convenience throughout their appearance here today.

Mr. Walerstein, if you are in the room, please come forward. The Chair will swear you in.

Are Mr. Gaul and Mr. Bennett in the room today?

[No response.]

Mr. Walerstein, you will take the oath at this time. Raise your right hand.

[Witness sworn.]

Chairman WYDEN. Mr. Walerstein, we will recognize you for any prepared remarks that you care to make at this time. Let the record also reflect the presence of a quorum at this time, the gentleman from New York, Mr. Engel and the gentleman from Virginia, Mr. Olin, both being in attendance.

Mr. Walerstein, we will, as with all witnesses, make your prepared remarks a part of the hearing record in their entirety. Please proceed to your oral presentation as you care to address the subcommittee.

TESTIMONY OF MICHAEL L. WALERSTEIN, PRESIDENT AND OWNER, MEDICAL MARKETING SERVICES, INC., PLANTATION, FL

Mr. WALERSTEIN. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, my name is Michael L. Walerstein. I am president and owner of Medical Marketing Services, Inc. [MMS], a marketing consulting firm incorporated in the State of Florida. With me today is my attorney, Mr. David Barmak, a partner in the law firm of Sherman, Meehan & Curtin, professional corporation, located right here in Washington, DC.

I am here today at the direction of the subcommittee. I understand that the subcommittee has been conducting an investigation into the cosmetic surgery industry and, in this regard, wishes to ask me questions pertaining to Medical Marketing Services.

Medical Marketing Services was incorporated in 1985 and, since that time, has operated as a marketing consultant in the United States. Specifically, MMS helps interested physicians learn how to market the phenol based chemical exfoliation procedure to their patients. For simplicity's sake, I will refer to this as the chemical face peel procedure.

Since the formation of MMS, my wife, Donna, and I have been the sole employees of the company. I am employed full time as president and Donna has worked on a part-time basis. Our offices are located in the suburbs of Fort Lauderdale, FL, and we are a small business in the true sense of the term.

With regard to my company, I wish to make clear that I am not a physician, nor is my wife. Medical Marketing Services does not perform or teach the chemical face peel process. Instead, our role as a consultant is to show physicians how they can best market the procedure through the use of media kits and other advertising methods. If the physician is not already familiar with this chemical face peel procedure, we contract with an experienced physician to teach the method. The teaching physician is not a staff member nor an employee of Medical Marketing Services and makes his or her own arrangements with the physician desiring instruction.

I am aware that the chairman of the subcommittee has expressed reservations about the chemical face peel process in general. I am not here today to debate the relative merits of this procedure as compared to the numerous other surgical and nonsurgical cosmetic procedures available to the public. That debate should be properly reserved for the experts in the area of plastic and cosmetic surgery. However, I will note that many esteemed and reputable physicians, including both cosmetic and plastic surgeons, believe

that the beneficial effects of the chemical face peel are both long lasting and relatively risk free when performed properly.

For the subcommittee's information, I have attached to my statement a copy of an article concerning the chemical face peel process which appeared in the Journal of the American Society of Plastic and Reconstructive Surgeons, Inc. in May 1985.

[The article referred to above may be found in the appendix.]

Although I have not attended the subcommittee's previous hearings on the cosmetic surgery industry, I have read several of the statements made by subcommittee members and witnesses. From this I have the sense that the concern is not just whether the various procedures are effective, but also who should be performing this elective cosmetic procedure.

I can address what I perceive to be two of the specific concerns as follows. First, with regard to the efficacy of the chemical face peel, I can only point to the medical articles I have read, such as the one I have attached to my statement, and to the hundreds of men and women I have spoken to and heard from who have had the procedure performed and who believe that it has made a dramatic improvement in their looks and their sense of self esteem. My wife, in fact, had the procedure performed 5 years ago and believes that this has made a significant improvement in the way she looks and the way she feels.

Based upon my experience, I believe the procedure to be a safe and proven nonsurgical procedure that can markedly improve the person's appearance and self confidence.

I, as well, am concerned with who should be performing the chemical face peel procedure, but perhaps my concern is somewhat different from those held by others. It is my understanding that many States allow nonmedical personnel to perform nonsurgical cosmetic procedures, such as the chemical face peel. I believe Florida is just one of those States. This allows individuals such as beauticians and other nonmedical individuals to perform the procedure legally.

My company has not, does not, and would not market this media package to nonphysicians. We believe that the procedure should be performed by a trained and licensed physician. We also believe that the rigorous medical training that licensed physicians undergo qualifies them to safely and properly perform this procedure. As part of our screening procedure, we require that the prospective clients send us their curriculum vitae and a copy of their current State medical license.

The real issue, as I perceive it, is that there is simply a competitive battle raging between members of the medical community as to who is going to reap the economic benefits of this lucrative market. To some extent, companies such as ours have fueled the demand for the procedure by helping to publicize the availability of this relatively inexpensive, effective procedure.

Another point with regard to the marketing of the procedure is that my company cannot and does not pass judgment upon whether an individual physician is a good or bad doctor. We must assume that because the physician is licensed and has undergone the rigors of medical training that he is qualified to perform the procedure. If the particular physician believes that he or she has the adequate

training and background to perform this procedure properly and effectively, then he or she may legally perform this procedure. There are many public and private authorities at both the State and Federal level whose job it is to monitor and evaluate a physician's performance and competency. I do not view that as my role.

However, my company does advocate the chemical face peel procedure. This procedure offers the patient a choice and an alternative to traditional cosmetic surgery. We believe it to be safer and more effective than many of the other expensive surgical procedures available to the public. This is a valid position held by many members of the medical community and the public.

Finally, if I may say so, I was pleased to read the comments of one of the members of this subcommittee who said the following at the panel's May 31, 1989 hearing:

> Misleading advertising and medical malpractice are not synonymous. The bad ad does not directly produce a bad surgical procedure. An unqualified practitioner could employ perfectly legitimate advertising, or for that matter, not advertise at all, and still perform bad surgeries. Similarly, it is conceivable that a qualified surgeon could place a misleading ad. So, the question we should ask today is, without advertising, would medical malpractice cease to exist?

The answer to the question posed by Congressman Hancock is a resounding no; clearly, malpractice occurs in the medical profession regardless of advertising, misleading or otherwise. As Congressman Hancock went on to note, the Federal Trade Commission has concluded that, after exhaustive study of the effect of advertising on the cost of medical services in the field of optometry, that the increased competition advertising has generated did not undermine the quality of health care and consumers have enjoyed considerable cost savings because of that advertising.

The problem does exist with respect to what should be done about false and misleading advertisements. I believe this area is one that requires rigorous enforcement to curb abuses. As the subcommittee is well aware, the Federal Trade Commission is conducting an investigation with regard to medical advertising. In this regard, I have furnished the Federal Trade Commission with examples of the advertising currently used by Medical Marketing Services.

We have cooperated with the Federal Trade Commission's investigation and believe that we will be able to satisfy fully the FTC's mandate to protect the public without impairing our ability to promote competition and to provide a service to the medical community. Thank you.

[Mr. Walerstein's statement may be found in the appendix.]

Chairman WYDEN. Mr. Walerstein, thank you.

The subcommittee has been told by several doctors who are now performing endodermology or exodermology procedures that you first came into contact with this procedure when your wife had the procedure done by a Mr. Ronald Bennett. Is that correct?

Mr. WALERSTEIN. Yes.

Chairman WYDEN. You mentioned in your written statement that your wife had the exodermology chemical peel 5 years ago. Would you please tell the subcommittee the name of the clinic where she had the procedure done?

Mr. WALERSTEIN. World Heath Exodermology Center, I believe.

Chairman WYDEN. Have you ever had a business relationship with Ronald Bennett in any company, particularly any involving the marketing and/or training of any medical procedure?

Mr. WALERSTEIN. Yes.

Chairman WYDEN. Which procedure specifically?

Mr. WALERSTEIN. In the marketing end.

Chairman WYDEN. In the marketing of what procedure, though. Exodermology and endodermology?

Mr. WALERSTEIN. Of the chemical peel.

Chairman WYDEN. But specifically exodermology and endodermology, isn't that correct?

Mr. WALERSTEIN. Would you repeat that question again, please?

Chairman WYDEN. Yes; the procedure that we're talking about here is an exodermology procedure or an endodermology procedure, isn't that correct?

Mr. WALERSTEIN. That's the name it went by, I guess.

Chairman WYDEN. Thank you.

Was World Health Research Center one of those companies?

Mr. WALERSTEIN. I had no knowledge of the workings of World Health Research. No; it was not one of those companies.

Chairman WYDEN. Mr. Barmak's letter to me, on July 27, 1989, and I quote: "Mr. Walerstein does not recall ever having heard of it." The question was about the World Health Research Center. It goes on to state, "No affiliation, no stock, no documents." I quote, "He, Walerstein, is not now and never has been an officer, director, or managing agent of World Health Research Center." That was the letter that was sent to me on July 27 1989.

But I have here—and I'm going to introduce it into the record—a promotional letter, a "Dear Doctor" letter, signed by Michael L. Walerstein, Director of Marketing, World Health Research Center, Inc. The letter states:

> An additional $200,000 to $400,000 can be added to your annual gross volume immediately when you are trained in our exclusive methods of exodermology. The nonsurgical face lift is now a perfected reality. World Health Research Center's exclusive system, with over 20 years of actual application and over 6,000 satisfied faces, has turned back the clock of time 10 to 20 years and more in the appearances of a wide variety of patients.

Now, there seems to be a significant difference between what you have described as your relationship with the World Health Research Center and with what Mr. Barmak has described as your relationship with the World Health Research Center in his letter of July 27.

So I will ask you again, did you have a relationship with the World Health Research Center, Inc.?

Mr. BARMAK. May we see a copy of the exhibit introduced into evidence?

Chairman WYDEN. I would be happy to have the staff show a copy of the exhibit at this time to the witness.

Mr. BARMAK. Thank you.

[Witness and counsel examining document.]

Mr. WALERSTEIN. I feel that can be best addressed by—it was approximately 5 years ago. I was involved briefly with Mr. Bennett. I never was an officer, nor was I a business associate, nor did I have any interest in the corporation in any stretch of the imagination. I

was, as I am now, a marketing consultant, independent marketing consultant.

Chairman WYDEN. Let me review again what we've been told. In the July 27 letter from Mr. Barmak with respect to the World Health Research Center, it states "Mr. Walerstein does not recall ever having heard of World Health Research Center." It goes on to state, "He's not affiliated with this organization. He's not now and has not been an officer, director."

I find it hard to understand how the statements square of counsel, "Mr. Walerstein doesn't recall ever having heard of World Health Research Center" and then goes on to state "he's not affiliated with this organization," when I've just given you a document, promotional material, signed by Michael L. Walerstein, director of marketing, World Health Research Center, Inc.

I find this very curious and would like to know who is correct here. Is counsel correct? Is this document a forgery? Has someone put your name on this? This seems to me to be a very curious state of events.

Mr. WALERSTEIN. I would say both statements are correct, in this respect. I cannot remember working for World Health Research Center, Inc. The affiliation that I did have was with World Health Exodermology. As I mentioned before, I was not an officer or an employee or associated with that company. I did independent marketing and there must have been some confusion.

Chairman WYDEN. The wording is very precise, Mr. Walerstein. That's why I'm asking it in a very methodical way. The letter from your counsel speaks of World Health Research Center, and states "Mr. Walerstein does not recall ever having heard of World Health Research Center," and your promotional material specifically is signed by you, Michael L. Walerstein, director of marketing, World Health Research Center. There's something inconsistent here. Counsel?

Mr. BARMAK. He answered it twice, Mr. Chairman.

Chairman WYDEN. Let us move on, now that we've established that you were, in fact, director of marketing of the World Health Research Center, Inc.

By unanimous consent, the Chair will have that document signed by Mr. Michael L. Walerstein, director of marketing, World Health Research Center, Inc., be introduced into the record at this time.

[The document referred to above may be found in the appendix.]

Chairman WYDEN. Now that this has been established, Mr. Walerstein, that you were director of marketing of the World Health Research Center, would you please describe what, if any, was Mr. Bennett's affiliation with the World Health Research Center?

Mr. WALERSTEIN. We knew Mr. Bennett to be Dr. Bennett, operating a clinic, World Health Exodermology Center, out of Fort Lauderdale, FL. He was, as we knew him then, to be the physician who did my wife's face after she saw an ad in the paper about the procedure. He was the owner, he was the decision maker, he was the boss in every sense of the word, and he was, as we knew him then, the physician.

Chairman WYDEN. Were you aware that Mr. Bennett was not a doctor? You said that you were of the view that he was, as I understood it.

Mr. WALERSTEIN. I was initially absolutely—initially not. We went in there. He operated as Dr. Ronald Bennett, I believe it was M.D.

Chairman WYDEN. So you are saying that Mr. Bennett misled you and led you to believe that he was a physician?

Mr. WALERSTEIN. He advertised as a physician, yes.

Chairman WYDEN. But you were misled, you personally?

Mr. WALERSTEIN. I can only speak for myself and my wife, and we both thought he was a physician.

Chairman WYDEN. All right. According to information provided to the subcommittee, former Dr. John Gaul and Mr. Theodore Levchenko were also associated with the World Health Research Center. What were their responsibilities with the center?

Mr. WALERSTEIN. I really—I do not know. I don't know what they did there.

Chairman WYDEN. In Mr. Barmak's July 27 letter to the Chair, he indicated that you briefly rendered services to the World Health Exodermology Center. What services did you provide and how long did you provide them?

Mr. WALERSTEIN. To the best of my recollection, it was about 5 years ago. My wife had the procedure done. We were thrilled by the results, really dramatic, very positive. I put together a marketing package for him and initially started to market this package to physicians.

As regards to the time, I'm saying maybe 2 to 4 months.

Chairman WYDEN. Now, we have another "Dear Doctor" letter from this particular center. This was once again signed by Mr. Walerstein as the director of marketing. I'm going to have staff show that letter to you as well.

By unanimous consent, we will ask that this letter be submitted into the record at this point also.

[The letter referred to above may be found in the appendix.]

Chairman WYDEN. Now, my question to you, Mr. Walerstein, is in the same fashion as with the World Health Research Center. It seems to me that the promotional material doesn't square with what your counsel has said. I'm anxious to try to ascertain what's really going on here. Your counsel says in the letter to me, of July 27, Mr. Walerstein is not affiliated with this organization, and the promotional material again says that you are director of marketing.

Is there anything more to this than what I see on the face of the document?

Mr. WALERSTEIN. I believe the statement in the letter from my attorney, Mr. Barmak, indicated that I am not affiliated. That's the truth. I am not affiliated with them. I was affiliated as an independent marketing consultant doing the marketing for the company.

Chairman WYDEN. The document seems to be quite clear to me, in terms of identifying you as the director of marketing. We will have the documents put into the record.

Mr. BARMAK. What——

Chairman WYDEN. Counsel, let me advise you again that you are not here as a witness. You are here to advise your client and are afforded a full opportunity to do so. But he is here as the witness.

Mr. BARMAK. I'm here, with all due respect, to protect my client.

I note that the document is undated, Mr. Chairman. I was only going to ask if you might be able to tell us the date of the document.

Chairman WYDEN. I believe the subcommittee doesn't have the date. All of Mr. Walerstein's documents are undated that we have found. That's why I asked if Mr. Walerstein wishes to assert that these documents are forgeries. The subcommittee is willing and anxious to hear the witness' views on this matter. But all of Mr. Walerstein's documents are undated.

Mr. Walerstein, isn't this "Dear Doctor" solicitation almost an exact copy of the solicitation from the previous one, the World Health Research Center?

Mr. WALERSTEIN. It would appear so, yes.

Chairman WYDEN. OK. Now, I have the cash flow projections from the World Health Exodermology Center, the center for which you appeared to have been the marketing director, according to the signature. As I understand this, it's a breakdown, month by month, of how much one of your doctor clients could expect to earn for each exodermology patient he treated.

For example, in the first month, allowing for expenses, if the doctor did 3 patients, he would net $4,610, and in the second month, with 5 patients, he would net $10,350, and so on up through the sixth month, where he would be netting $24,700 doing peels on 10 patients.

As the marketing director, were you responsible for developing these projections?

Mr. WALERSTEIN. No.

Chairman WYDEN. Do you know who was?

Mr. WALERSTEIN. Yes.

Chairman WYDEN. Who was that?

Mr. WALERSTEIN. Those were supplied by Ronald Bennett, based on the amount of patients that he did over those periods of time.

Chairman WYDEN. Now, according to this, the medical supplies for doing an acid peel are about $150 per patient. Yet the cash flow materials that the subcommittee has show doctors are encouraged to charge the patient $3,500 for the face peel. This appears to be a pretty significant profit margin.

What about this procedure warrants these kinds of profits?

Mr. WALERSTEIN. You're looking at only one expense. There are other expenses involved in this, such as marketing, ongoing local public relations. I do not know if you're aware of it or not, but our physicians also provide—encompassed in that is an 8-day, post-treatment care facility which supplies all the medication that is needed, all of the costs of putting the patient in the facility. So it's an inclusive price. It's not just the cost of the chemicals.

Chairman WYDEN. Many physicians who do this procedure have told the subcommittee that they routinely charge between $900 and $1,000, $900 and $1,100, for a face peel. What justifies the additional margin that you're talking about?

Mr. WALERSTEIN. As I mentioned before, the cost of putting a patient through post-treatment care, I don't believe—and I don't know—but I don't believe you're judging apples for apples here. I think those people do this same treatment on an outpatient basis.

Our physicians, for the most part, take care of the patients for 8 days, post treatment.

Chairman WYDEN. It looks like a $1,500 profit per patient to me, but we will further examine your views on this.

Now, it's our understanding that you've been in marketing all your life, and it looks to me like you're suggesting to your clients that they spend about 50 percent of their first months' budget on advertising. Is that a sound business practice?

Mr. WALERSTEIN. Yes.

Chairman WYDEN. Sound if you're interested in making money.

Mr. WALERSTEIN. Yes.

Chairman WYDEN. That's what you're really interested in, making money.

Mr. WALERSTEIN. I believe that's capitalism.

Chairman WYDEN. Mr. Bennett, Mr. Gaul, and Mr. Levchenko, also associated with the World Health Exodermology Center, what were their capacities there at the center?

Mr. WALERSTEIN. I don't know the answer to that. I was involved in marketing on it. I was an outside subcontractor. I didn't get involved in the day-to-day operation of what was going on there.

Chairman WYDEN. As I understand it, you're currently the marketing director and owner of Medical Marketing Services, Inc. I would like to have the staff show you another one of the "Dear Doctor" letters at this time.

Mr. Walerstein, is this one of your current "Dear Doctor" letters that promises doctors they can add up to $400,000 in their annual profits?

Mr. WALERSTEIN. No.

Chairman WYDEN. What exactly is it? I find this very mystifying because these are all documents with your name on them. They say Medical Marketing Services, Inc., they say you can make up to $400,000 in profit, and they have your signature on them.

Mr. WALERSTEIN. The way you asked the question, the answer is no. If you'd like to rephrase the question, I would be happy to address it, sir.

Chairman WYDEN. What is the document then?

Mr. WALERSTEIN. This is a letter that we have used up to fairly recently, not currently using it now, describing our program, or our initial program, to physicians.

Chairman WYDEN. Over what period did you use that letter?

Mr. WALERSTEIN. I would say 2 or 3 years, possibly, with modifications here and there.

Chairman WYDEN. When did you stop using it?

Mr. WALERSTEIN. We're still using one similar, but we made some changes in the letter.

Chairman WYDEN. What changes have you made in it?

Mr. WALERSTEIN. I haven't had a mailing in 6 months, Mr. Chairman, so—and I haven't reviewed the new ones that have come off the press. I don't have one here to show you, so I would rather just wait until I have one for you.

Chairman WYDEN. Do they make any changes in the amount of profit that it is suggested a physician could make?

Mr. WALERSTEIN. In our letters, we don't suggest profit. If you'd be kind enough to read my letters, we suggest income.

Chairman WYDEN. Really? It says that up to $400,000 can be added to annual gross volume immediately.

Mr. WALERSTEIN. Excuse me. Gross and profit are two different numbers, Mr. Chairman.

Chairman WYDEN. OK. What's the profit?

Mr. WALERSTEIN. What's the profit? What profit?

Chairman WYDEN. If you do it on the basis of these cash flow projections?

Mr. WALERSTEIN. We have never found the exact numbers to work specifically across the board. Every physician's costs are different, every physician's overhead is different, every physician's success is different. It would depend on the individual physician.

Chairman WYDEN. What's the expected profit?

Mr. WALERSTEIN. On what?

Chairman WYDEN. On a patient who has this particular procedure done.

Mr. WALERSTEIN. It would be dependent, once again, where the physician was located, how efficient he was, how well he followed his business talents, his personality, known as a bedside manner. Some physicians have differences ranging from quite a bit. You would really have to speak with the individual physician to find out what his profits are, what his net profits are.

Chairman WYDEN. What we're really talking about, though, are virtual carbon copies from the World Health Exodermology Center, the World Health Research Center, and the Medical Marketing Services, Inc., all telling doctors that they could add up to $400,000 to their annual gross volume immediately; isn't that correct?

Mr. WALERSTEIN. Yes; that is.

Chairman WYDEN. All right. Why so many different company names, Mr. Walerstein? That's why I've been trying to go slowly through the names on all these different documents. Why so many, since it seems to be the same medical procedure, using the same training, using the same advertising, using virtual carbon copies of these letters; why so many names? The same profit, same cash flow arrangements?

Mr. WALERSTEIN. I can address Medical Marketing Services, which is my company, has only used one name, and it has been the same name since 1985. These other companies, where the letter appeared World Health Research and World Health Exodermology, were not my companies. I was merely an independent marketing consultant for these companies.

Chairman WYDEN. I want to recognize my colleagues. I just want to say that the most recent letter, does specifically address the profit question—and this will be in the record. This is the Medical Marketing Services, Inc. letter. It states, "Our marketing methods can eventually produce an additional gross income of $400,000 and more annually, year after year, without appreciably increasing your current practice overhead." So let the record show that the most recent letter does deal specifically with the question of profits, and also, one of the earlier letters from the World Health Research Center states, "Your marketing area can eventually produce an additional gross of $½ million and more annually, year after year, without increasing your current practice overhead, and in the

area of 70 percent gross profit." So the letters do address the profit question.

Mr. BARMAK. Mr. Chairman, may we see copies of letters, since you've referred to them and are putting them in the record?

Chairman WYDEN. You have all three of them. The World Health Research Center was the letter I showed you first and asked questions about first; the Medical Marketing Services, Inc. letter was the letter I asked about third, which you also have a copy of, counsel.

Mr. BARMAK. Something about your comment had suggested that these were new and different letters than those given to us. Thank you, Mr. Chairman.

Chairman WYDEN. OK. Let me recognize my patient colleagues. I know the gentleman from New York is on a tight schedule, and the gentleman from Virginia has been very patient.

The gentleman from New York.

Mr. ENGEL. Thank you, Mr. Chairman.

Mr. Walerstein, I have listened very carefully and also read your testimony, and the statement you issued after your testimony involving contact with the subcommittee. If I can summarize it, you are actually saying that you basically market this procedure and you are not really involved in whether or not it's safe—that's not a concern of yours—that you assume the States regulate it, and if there is regulation or lack of regulation, you just assume it's all right. Does that basically capsulize your comments?

Mr. WALERSTEIN. With all respect, Congressman Engel, you've asked me three questions. It would be unfair for me to give one answer to three questions. If you'd like to break them down, I would be happy to address them, sir.

Mr. ENGEL. Could you break them down, since I thought it was only one question and you find three.

Mr. WALERSTEIN. What's your first question, sir?

Mr. ENGEL. I thought I only asked one question.

My question was, are you basically saying that you are responsible for marketing and that you believe the regulation as to the safety or lack of safety of the procedure is something that you don't concern yourself with?

Mr. WALERSTEIN. No; that's not correct.

Mr. ENGEL. Could you tel' me where I'm wrong, please?

Mr. WALERSTEIN. Yes, sir. We are basically, totally, a marketing public relations company. We're not involved in the medical aspect of it. But our concern for the safety of the patients is utmost in our mind, and the concern of the well-being for the patients is utmost in our mind. So I don't think there's a division of one without the other in your question. You have to look at it both ways.

Mr. ENGEL. If that's true, Mr. Walerstein, is it not true that most of your training is done by John Gaul, who we've established in the subcommittee is no longer a licensed physician?

Mr. WALERSTEIN. That is correct.

Mr. ENGEL. So I don't understand how you can make the first comment and say that I'm correct in this question. Wouldn't it stand to reason that you would want to make sure that you had a licensed physician doing the training if your concern was safety and well-being of the patients?

Mr. WALERSTEIN. May I address that question?

Mr. ENGEL. Sure.

Mr. WALERSTEIN. We would have. Traditionally, we are concerned with safety, and in regards to Dr. John Gaul and any licensure problems he might have had, none of them were the result of his many years of experience with this procedure. There are, to the best of my knowledge, no complaints in the many hundreds, perhaps thousands, of faces that he's done with regard to the success of his procedure.

We also train the physician at his location. I think any of us would be hard pressed to find a physician that's licensed in all the 50 States.

The last part of that I want to address is that traditionally, in medicine, a large portion of training is done by people who are not licensed physicians. If you'd like, I could cite some examples for you, Congressman.

Mr. ENGEL. Certainly.

Mr. WALERSTEIN. OK. In the orthopedic industry, for one, an appliance manufacturer does not send out a licensed physician to teach another physician how to insert a new knee or a new hip or a new elbow, normally. They send lay people who are technicians, who are not licensed physicians, who are experienced in that aspect of that procedure, who are in the ORs, who are scrubbed, who work side by side with the physician, instructing him how to do it.

Now, there's another aspect that I think might help clarify this one more time for you. In the medical industry, traditionally there is a saying that is as old as medicine. "See one, do one, teach one." Many, many difficult procedures, heart procedures, surgery of all different types, are done by a physician who will go away for a day or two, see a procedure or two being done, talk about it, maybe get hands on, and then go home and do the procedure. So traditionally, not all training in medicine is done by currently licensed physicians.

Mr. ENGEL. How many of your trainers have had their licenses revoked due to malpractice?

Mr. WALERSTEIN. In the last 4½, 4 years, I've only had one trainer—Dr. Gaul.

Mr. ENGEL. Is he the only trainer that has had his license revoked, or has he been your only trainer? Because if he's been your only trainer, then your answer is 100 percent.

Mr. WALERSTEIN. To the best of my knowledge, he has been my only trainer for about 3 or 4 years, yes.

Mr. ENGEL. Is there any type of doctor whom you would not sell your marketing package to? For instance, if a psychiatrist, who is a medical doctor, wanted to perform this, would you sell your package to him?

Mr. WALERSTEIN. If he met our standards, and if he was currently licensed, and if his CV showed that he, in fact, was a medical doctor, he was a medical doctor before he was a psychiatrist, certainly.

Mr. ENGEL. Your marketing literature, I understand, tells the doctor, that he can be trained in just 1 week. Can you tell me what you train in 1 week?

Mr. WALERSTEIN. I don't train doctors, and I'm not involved with training physicians. Once again, I'm a marketing consultant. The medical training is in the hands of the people that train the physicians. I don't pass on the criteria or anything. This is not my expertise. I'm not a physician.

Mr. ENGEL. I understand that. But the literature does say that a doctor can be trained in just 1 week.

Mr. WALERSTEIN. Yes.

Mr. ENGEL. That seems to me to be an awfully short amount of time to be able to train someone who is then performing a procedure on a patient that can potentially be very dangerous. Wouldn't you agree?

Mr. WALERSTEIN. No.

Chairman WYDEN. If the gentleman will yield on that point, the gentleman is correct in saying that the training will last 1 week, and it is you, Mr. Walerstein, who has signed the letter. You have stated that you are not involved in the training, but the fact is that you are the one in the promotional material who asserts that a qualified doctor can be trained, in your words, in just 1 week.

I appreciate the gentleman from New York yielding on that.

Mr. ENGEL. Thank you. The question I have and the concern that I have, my concern is not your making money or anything like that. Obviously, you're in business to make money. My concern is that in your letter soliciting doctors' business, you say that this procedure is—I'm quoting—is a safe, proven system. Obviously, you're aware that there can be very serious complications, even deaths, resulting from acid peels. I don't know that I would call it a safe, proven system. That's really my concern, that here we're packaging something that's really potentially dangerous to the public.

Mr. WALERSTEIN. I share that concern, and I share your interest in protecting the public. We feel, through our experience, that this procedure, when properly performed, on a patient that fits the protocol, has a much higher safety record, a much more satisfied record, and less instances of complications than normal cosmetic surgery, and I think if you would query any of your facts and figures, it probably would be borne out.

Mr. ENGEL. What concerns me, Mr. Walerstein—and I don't think this is unfair, but I would like your comment on it—it seems to me that your marketing letters totally ignore the potential risks and uses as its hook the profits to be made and the fullproof nature of the chemical peel. We all have a way of perhaps accentuating what we would regard as the positive and downplaying the negative, but don't you think that's a little bit irresponsible?

Mr. WALERSTEIN. This letter is basically for the physician—excuse me. Let me phrase it another way.

When a physician comes down to meet with us, and before he considers getting involved in the medical aspect of the procedure, we give him references to talk to, we encourage him to take time and seek out information at his medical library, do all the research that he can possibly do, and let him make his decision. Our point is, as marketing consultants, to expose the physician who is interested in doing this, if he has the necessary qualifications, giving him the tool to do this—you know, from the marketing aspect.

So really, this is just initially. There are meetings involved, and we encourage the physicians to really check us out and to check the procedure out and take their time. Some of them have taken as long as 6 or 7 months before they made up their mind.

Mr. ENGEL. I'm a little bit confused. Mr. Chairman, this will be my final question.

Why would a doctor pay you $50,000 to learn—I realize there's some marketing involved—but to learn a procedure and obtain a formula that has really existed for decades, one that can be found in a standard medical textbook on the subject?

Mr. WALERSTEIN. That's an excellent question. My answer to that would be—is that you could learn any procedure possibly on your own. But to make it successful and to make it a successful part of your practice, and to build the necessary components into that procedure to make it work, that's what they're paying for. They're paying for our marketing services, our support material, our public relations and our experience in the field.

Mr. ENGEL. OK. Thank you. You mentioned—you just used the word successful?

Mr. WALERSTEIN. Uh-huh.

Mr. ENGEL. You mean medically successful, or are you just referring to financially successful?

Mr. WALERSTEIN. We first have to look at the patient and the success of the procedure, of course. But the physician could have, and many of them do have, the finest procedural talents and know how to do many wonderful procedures, but unfortunately, they don't know how to operate the business end or the marketing end of it. That's what they're paying us for.

Mr. ENGEL. Are you aware of—I know I said this would be my last question, so if you would just indulge me, Mr. Chairman, this will be the last question.

Chairman WYDEN. That's quite all right.

Mr. ENGEL. The doctors who you train, not the doctor who does the training, the doctors whom you train, how many of them have had their licenses revoked for malpractice? Are you aware of any of those?

Mr. WALERSTEIN. Outside of the physician in Oregon?

Mr. ENGEL. Including those.

Mr. WALERSTEIN. One.

Mr. ENGEL. You're not aware of any other doctors?

Mr. WALERSTEIN. Not that I'm aware of, sir.

Mr. ENGEL. OK. Thank you, Mr. Chairman.

Chairman WYDEN. Thank you. We're also pleased to have another of our colleagues from New York, the other end of the State, Mr. McNulty.

Mr. MCNULTY. I have no questions at this time, Mr. Chairman.

Chairman WYDEN. I thank my colleague. Let me go back to this point about why so many different company names. You know, Mr. Walerstein, we've established you're the director of marketing for Medical Marketing Services, Inc., Health Exodermology Center, and World Health Research Center, or were at a given time. I'm still not clear on why so many different company names.

Mr. WALERSTEIN. Let me once again try to help you out, if I may.

When I originally worked with whom we thought was Dr. Bennett, he had exodermology. After we found out that he was, in fact, not a real doctor, we left him and started Medical Marketing Services, and Medical Marketing Services has been intact since 1985.

Chairman WYDEN. OK. When you started your relationship with Mr. Bennett, that was at what company?

Mr. WALERSTEIN. Excuse me. I started a relationship with who I believed was Dr. Bennett.

Chairman WYDEN. OK. What company was that, and when was it?

Mr. WALERSTEIN. I believe it was—and you'll excuse me; that was 5 years ago, so if I'm a little rusty on this—I always believed I was dealing with World Health Exodermology Center, but according to this letter, there might have been a mailing or two under World Health Research Center. But it was basically World Health Exodermology, I believe, to the best of my knowledge.

Chairman WYDEN. So you think that mailings went out incorrectly as well?

Mr. WALERSTEIN. I didn't say that.

Chairman WYDEN. I'm trying to follow exactly what you said. You said that Mr. Bennett started with you at World Health Exodermology Center, but some mailings went out under World Health Research Center.

Mr. WALERSTEIN. It might have. I didn't start with Mr. Bennett. I started with who I believed was Dr. Bennett.

Chairman WYDEN. Right. OK. So we started with the person you thought was Dr. Bennett, World Health Exodermology Center, and he turned out not to be Dr. Bennett. Did you move next to World Health Research Center?

Mr. WALERSTEIN. Both the world health corporations were fully owned and controlled by the person that I knew to be Dr. Ronald Bennett. I had no vested interest in the corporations, I owned no stock in the corporations, I was not an officer in the corporations. I never had any interest in World Health, either center, or exodermology or research center.

Chairman WYDEN. Did you pay Mr. Bennett, or Dr. Bennett, if you want to characterize him, anything?

Mr. WALERSTEIN. Yes; I did.

Chairman WYDEN. How much did you pay him?

Mr. WALERSTEIN. I paid him—I think it was $5,000 for the rights to market this program, the rights to develop and market a program.

Chairman WYDEN. When was that?

Mr. WALERSTEIN. It must have been shortly after we were so happy with the way my wife looked from her results of this procedure. I'm guessing maybe 5, maybe 6 years ago.

Chairman WYDEN. So you paid him essentially for the rights to own the program?

Mr. WALERSTEIN. No; I did not.

Chairman WYDEN. The rights to market the program.

Mr. WALERSTEIN. Yes; I did.

Chairman WYDEN. OK. We have a vote on the floor of the House at this juncture, Mr. Walerstein. I appreciate your patience. We're

going to have to take a break at this time. Let us try to reconvene again in 15 minutes.

Mr. WALERSTEIN. Yes, sir.

[Whereupon, the subcommittee was in recess.]

Chairman WYDEN. The subcommittee will come back to order. The Chair notes the presence of a quorum, the gentleman from New York and the gentleman from Missouri and the Chair. Mr. Walerstein, our thanks again for your patience. This has been a long day and we appreciate your assistance in going forward.

What was the gross income of your company in its best year, Mr. Walerstein?

Mr. WALERSTEIN. What is the pertinency of this question to the subject under inquiry, Mr. Chairman?

Chairman WYDEN. The Chair is looking particularly at the nature of medicine being marketed as big business and has been very explicit in that regard. If the witness declines to answer, the witness should state that he does and why.

Mr. WALERSTEIN. What is the subcommittee's authority to investigate that subject?

Chairman WYDEN. Pursuant to rule XI, as the Chair noted in his opening statement, the subcommittee has oversight jurisdiction over all matters relating to small business. Cosmetic surgery happens to be one of the fastest growing small businesses in the country.

Mr. WALERSTEIN. I can't hear. There's too much noise out there.

Chairman WYDEN. The witness is exactly right. There is considerable noise. Can the staff get that door shut?

Mr. Walerstein, I think you heard—I cited rule XI as the rule authorizing this subcommittee to pursue, as part of its oversight jurisdiction matters relating to small business. It's pursuant to that authority that the Chair read in his opening statement that this hearing is being held.

Mr. WALERSTEIN. Mr. Chairman, I respectfully decline to answer the question on the grounds that it is outside the proper scope of this subcommittee's activities. I respectfully decline to answer the question on the grounds that it would violate my constitutional rights, including rights granted to me by the first and the fifth amendment.

Chairman WYDEN. The Chair is going to ask that you claim a specific constitutional right for not answering the question, Mr. Walerstein. I'm not——

Mr. BARMAK. He just did, Mr. Chairman. He claims several specific constitutional rights.

Chairman WYDEN. I believe, and am so advised by House counsel, that the pertinency of the question has been adequately established and I overrule your objection with respect to pertinency.

Mr. BARMAK. We respectfully disagree with your interpretation in that regard and, in any event, Mr. Walerstein has invoked additionally his rights under the first and fifth amendments of the Constitution.

Chairman WYDEN. What right under the first amendment do you claim, Mr. Walerstein?

Counsel is here to advise his client, and the Chair would admonish him to do so.

Mr. WALERSTEIN. I am not an attorney, and I've been advised by my counsel that I am protected under the rights given by those amendments.

Chairman WYDEN. Mr. Barmak, let me address this question to you, then. What rights specifically under the first amendment are you addressing?

Mr. BARMAK. Most particularly, the right to privacy.

Chairman WYDEN. The Chair rules, on the basis of that right on the advice of counsel, that that claim is overruled.

What right under the fifth amendment are you claiming, Mr. Barmak?

Mr. BARMAK. Due process rights and the right against self-incrimination. With all due respect, Mr. Chairman, I can advise you, just in the hope that this might expedite things, that Mr. Walerstein will not answer these questions, notwithstanding the overruling of the objection.

Chairman WYDEN. With regard to his claim of due process, on the advice of House counsel, the Chair overrules that.

With respect to his rights against self-incrimination under the fifth amendment rights, Mr. Barmak, the witness should so specifically state his claim.

Mr. BARMAK. Do I understand you wish him to reiterate his objection to your question, Mr. Chairman?

Chairman WYDEN. The witness should state his right under the fifth amendment claim against self-incrimination. This would be a specific claim with respect to self-incrimination.

Mr. WALERSTEIN. In addition to those rights already invoked, I respectfully decline to answer that question on the grounds that it may tend to incriminate me.

Chairman WYDEN. The Chair will reserve judgment on that claim, Mr. Walerstein, and we will move on to several other areas.

Now, it's my understanding that Mr. Gaul's medical license was revoked after he was arrested in 1984—and I quote here—arrested in 1984 for prescribing drugs inappropriately to an undercover policewoman who was posing as a prostitute.

Now, you have said you were aware that Mr. Gaul didn't have a medical license. Were you aware of this matter that I've just described, that he was arrested in 1984 for prescribing drugs inappropriately to an undercover policewoman who was posing as a prostitute?

Mr. WALERSTEIN. Excuse me. The person you're referring to, whether licensed or not, is still a fully—he's a physician, so he's called Dr. Gaul.

Chairman WYDEN. All right.

Mr. WALERSTEIN. He told me his version of the story some time ago.

Chairman WYDEN. When was that?

Mr. WALERSTEIN. Several years ago. I don't know precisely.

Chairman WYDEN. What did he tell you?

Mr. WALERSTEIN. He told me that a patient—to the best of my knowledge, now, once again—he told me that the patient came in with a sob story and a crying story, and a story about family and this type of thing and not prostitution, and he prescribed. But that's what he told me.

Chairman WYDEN. You continued to use him, though, as a trainer, after you were aware that he was arrested in 1984 for prescribing drugs inappropriately to an undercover policewoman who was posing as a prostitute?

Mr. WALERSTEIN. As I mentioned to you prior, previously, the man has been doing this procedure in question for many years, and to the best of my knowledge, and the knowledge of anybody else I'm aware of, the man never had any complications or problems in this procedure, plus he was the best person that we have been able to find to train our other physicians up to this point.

Chairman WYDEN. I still would like to ask the specific question. Did you use him as a trainer after you were aware that he was arrested in 1984 for prescribing drugs inappropriately to an undercover policewoman who was posing as a prostitute, yes or no?

Mr. WALERSTEIN. The answer is yes.

Chairman WYDEN. Thank you. Now, according to this same article, Mr. Bennett's enterprises extended well beyond chemical peels. Among Mr. Bennett's ventures included the creation of "an elaborate health spa and research center on the Caribbean Island of Anguilla." His investors allegedly include Bob Guccione, Penthouse Magazine publisher.

Were you affiliated with Mr. Bennett in this business as well?

Mr. WALERSTEIN. No.

Chairman WYDEN. Let me ask you some additional questions. I want to recognize my colleagues for any they would like to ask at this time.

Does the gentleman from Missouri desire to ask some questions at this time?

Mr. HANCOCK. Not at this time.

Chairman WYDEN. The gentleman from New York.

Mr. MCNULTY. I have no questions, Mr. Chairman.

Chairman WYDEN. All right. Let me ask just a couple of other questions then.

Mr. Walerstein, it's my understanding that in 1986 the Florida State Department of Professional Regulation received a complaint that you were practicing medicine without an active license. Is that correct?

Mr. WALERSTEIN. I don't know when it started, but I heard about it about, oh, a year ago. I didn't know I was under investigation.

Chairman WYDEN. Florida's subsequent investigation focused on your chemical peel franchising business. State regulators were concerned about who trained your doctor clients, the risk to patients, and who you would and would not train. Is that correct?

Mr. WALERSTEIN. Once again, I was not aware of the specifics of the investigation.

Chairman WYDEN. Florida took no action against you. Can you explain why?

Mr. WALERSTEIN. I can't answer that. I didn't even know that there was an investigation, and the investigation was over when I first heard that there was an investigation.

Chairman WYDEN. Florida's investigative closing order concluded that their investigation substantiated the allegation that you were practicing or attempting to practice medicine without an active license, in that you were attempting to instruct physicians in the

area of chemical face peeling. However, your case was closed because your—and I quote—"unlicensed activity had ceased and you could not be located at that time."

Is that your understanding of the way this matter was resolved in Florida's investigative closing order?

Mr. WALERSTEIN. Absolutely not.

Chairman WYDEN. You aren't aware of this closing?

Mr. WALERSTEIN. No.

Chairman WYDEN. Did you dissolve Medical Marketing Services?

Mr. WALERSTEIN. No.

Chairman WYDEN. Did you tell the State of Florida that you had?

Mr. WALERSTEIN. I never spoke to the State of Florida on any matter.

Chairman WYDEN. Did you get a letter from the State of Florida with respect to this matter and talk to them on or about March of 1987?

Mr. WALERSTEIN. Not that I'm aware of. I can't remember—no; I don't think I ever spoke to them about it.

Chairman WYDEN. Did you ever meet with a Mel Waxman, who is an investigator from the Florida State regulatory authorities?

Mr. WALERSTEIN. I don't remember meeting with anybody by that name.

Yes; I did meet with somebody, I did, by the name of Mel Waxman, and he did inquire—I think Mel Waxman was his name. I think he was an ex-New York cop or something. He asked me about it and I said well, I've never done a procedure, I'm not a medical doctor, I've never had a patient, and that's the last I ever heard of that.

Chairman WYDEN. You never told the State of Florida that you dissolved Medical Marketing Services?

Mr. WALERSTEIN. Not that I'm aware of.

Chairman WYDEN. Let me read you from the State of Florida, Department of Professional Regulation, Medicine Board Case No. 007A163, a complaint made by Dr. Nathan... The relevant portions of the closing order are "Investigation substantiated the allegation that subject was attempting to instruct physicians in the area of chemical face peeling. Subsequent investigation reflects that subject's company was dissolved and subject is unable to be located at this time." It goes on to say, "As the unlicensed activity has ceased and subject cannot be located at this time, this case should be closed." State of Florida, Department of Professional Regulation, Medicine Board Case 0078163.

Mr. BARMAK. May we see what you've read from, Mr. Chairman?

Chairman WYDEN. I'll have staff give it to you at this time.

Let us do this. I'm going to have to have staff make sure that the confidentiality of the claimant is protected in this regard. We will move on in this regard.

But you are stipulating, Mr. Walerstein, that you did meet with an investigator from the Florida regulatory authorities, Mr. Waxman?

Mr. WALERSTEIN. The name sounds familiar, yes.

Chairman WYDEN. What did you feel when you learned about what happened in Oregon, where the physician who had received the training, the chemical face peel training, performed it on a

woman in my congressional district and the woman died, and the license of the physician was revoked? It was really a very tragic set of circumstances, it seems to me, all around. What was your feeling about that, Mr. Walerstein? Did you feel anything needed to be altered about the service and the cosmetic surgery procedure that you're associated with?

Mr. WALERSTEIN. Mr. Chairman, you asked me several questions in one sentence. Which question would you like me to address first?

Chairman WYDEN. First, did you alter any of the services that you're associated with after the tragedy in Oregon?

Mr. WALERSTEIN. No.

Chairman WYDEN. You didn't feel that what happened in Oregon in any way related to the service that you're associated with?

Mr. WALERSTEIN. I was horrified when I heard of the tragedy that happened in Oregon.

Chairman WYDEN. Wasn't that doctor trained by Mr. Gaul, who you are associated with?

Mr. WALERSTEIN. No; he was trained by Dr. Gaul.

Chairman WYDEN. OK. So you are associated with Dr. Gaul, or Mr. Gaul. I've described to you the circumstances about the arrest that was made, I believe, in 1984, and you felt that even though this was horrifying, there was no need to in any way change the services that you're associated with?

Mr. WALERSTEIN. Briefly, I was horrified when I heard about the Oregon situation. When I spoke to the doctor in question, I was also informed that she was a very difficult patient and it was a tragedy on what happened, but that she refused post-treatment medical care. That's, once again, what I was told.

Chairman WYDEN. Why did the Oregon Board of Medical Examiners revoke the physician's license—and let me just read you again from the opening statement made by the Chair. Dr. Johnston specifically said, "The Oregon Board has recently revoked the license of a physician who is a franchise physician doing face peels. He killed an elderly lady whose post-operative care was entrusted to an untrained person in a local motel."

Mr. WALERSTEIN. Tragic, tragic.

Chairman WYDEN. But you felt that this was in no way associated with the service that you provide? What happened in Oregon is absolutely unrelated? Dr. Gaul or Mr. Gaul trained the person in Oregon, and then the physician performed the procedure. Dr. Johnston has described it specifically. I've read it several times. But you feel that in no way the service that you provide had anything to do with what happened in Oregon?

Mr. WALERSTEIN. That's not a correct—no; that's not correct.

Chairman WYDEN. Then state for us what you changed after what happened in Oregon, or what your assessment is of how this tragedy took place. The Oregon Board of Medical Examiners is real specific, Mr. Walerstein, and I would be interested in having your specific assessment of what took place.

Mr. WALERSTEIN. I was horrified when the doctor called me and told me about the problem. I asked him if he felt in any way that it was a result or a direct result of this procedure, which is an accepted medical procedure—it's been around for years. And he informed

me that he felt not. I asked him if it had anything, you know, that there was anything that was a direct result, and he told me that he thought not.

Chairman WYDEN. You felt that, in spite of the fact that the Oregon Board of Medical Examiners revoked his license, that this had nothing to do with your service?

Mr. WALERSTEIN. Once again, not being a medical person, once again, not being involved with the medical aspect of the procedure, being a marketing consultant, I really don't feel that I have the judgment to pass on the medical industry. You know, that's not my expertise and that's not my field, sir.

Chairman WYDEN. How many physicians has Medical Marketing Services sold your product or service to?

Mr. WALERSTEIN. Offhand, I don't know, but I would say in the area of maybe—oh, God, over 50 or 60.

Chairman WYDEN. Is there a doctor in my home State that now has the exclusive rights to your procedure?

Mr. WALERSTEIN. No.

Chairman WYDEN. Are there doctors in my home State who are continuing to use your procedure?

Mr. WALERSTEIN. Once again, it's not my procedure. This is a medical procedure that's been around longer than any of us sitting here today.

Chairman WYDEN. The procedure you've been associated with.

Mr. WALERSTEIN. What we have is our marketing aspect of it and our business end of it. That's our proprietary business.

To the best of my knowledge, there is.

Chairman WYDEN. One physician, two physicians, three physicians?

Mr. WALERSTEIN. Currently, one.

Chairman WYDEN. But he doesn't have an exclusive right?

Mr. WALERSTEIN. No.

Chairman WYDEN. Do you know how much he charges for a procedure, and how much you charged for your particular service to him, Mr. Walerstein?

Mr. WALERSTEIN. I don't know what he charges.

Chairman WYDEN. How much do you charge?

Mr. WALERSTEIN. I think I charged possibly $40,000 or $45,000.

Chairman WYDEN. Is this particular individual in Oregon also one who has been trained by Dr. Gaul, Mr. Gaul?

Mr. WALERSTEIN. I believe so.

Chairman WYDEN. Do you know when that training took place?

Mr. WALERSTEIN. No.

Chairman WYDEN. Was it after the death of the elderly woman in Oregon?

Mr. WALERSTEIN. I don't know. The doctor makes his own medical training arrangements.

Chairman WYDEN. Let's just finish the matter of the State of Florida, Department of Professional Regulation. We will have the staff give you these two documents.

My question, Mr. Walerstein, is that the State of Florida obviously believes that this is not going on any longer, as the document states——

Mr. WALERSTEIN. I'm sorry, I couldn't hear you.

Chairman WYDEN. The State of Florida obviously believes that this marketing and this service is not going on, and yet you have told me it still is. You're not at all familiar with those documents with respect to the complaint and those materials?

Mr. WALERSTEIN. I am not familiar with these documents. I don't believe that—I know for a fact I've never seen this one here.

Chairman WYDEN. Which one, if you would state for the record.

Mr. WALERSTEIN. Who's Bruce Lamb?

The closing order I've never seen before, and I may have seen this letter before, but I can't swear to it.

Mr. BARMAK. Mr. Chairman, is the closing order a redacted version of that order? It appears to me not to be a complete document. I was wondering if you understand it to be an incomplete version we've been provided.

Chairman WYDEN. I think the subcommittee doesn't have anything more than that from the State of Florida.

Are you concerned, Mr. Walerstein, at this point, that the State of Florida is going to be concerned that you're still in business? They obviously think you aren't right there.

Mr. WALERSTEIN. No; I'm not concerned with the fact, because if we're talking about performing medical procedures here, I've never performed medical procedures, and I'm not a doctor.

Chairman WYDEN. But you have not told the State of Florida that you have dissolved your activities and services?

Mr. WALERSTEIN. To the best of my knowledge, no.

Chairman WYDEN. I guess there's only one other question that I want to make sure we're clear on. The doctors pay you $40- or $45,000 for this service that you perform. Do you pay Dr. Gaul out of that?

Mr. WALERSTEIN. As an independent contractor, yes.

Chairman WYDEN. What do you pay him?

Mr. WALERSTEIN. I pay Dr. Gaul currently $7,000 as an independent subcontractor to teach physicians how to do this procedure.

Chairman WYDEN. Even though he's had his license revoked?

Mr. WALERSTEIN. I pay Dr. Gaul $7,000 to do this procedure.

Chairman WYDEN. But you are aware that he has had his license revoked?

Mr. WALERSTEIN. Yes.

Chairman WYDEN. The subcommittee staff has just informed me that he's had his license revoked.

Mr. WALERSTEIN. Yes.

Chairman WYDEN. Dr. Gaul goes around the country and trains people and you pay him directly, even though he's lost his license, and we talked about the——

Mr. WALERSTEIN. The corporation pays him, yes.

Chairman WYDEN. He's lost his license, and we talked about the matter of the arrest. But you have no qualms about him going out and doing this training, not on the basis of what happened in Oregon or anywhere else?

Mr. WALERSTEIN. As a result that the doctor had never had any complaints in regards to this procedure, or nothing that I was aware of as far as the quality of his ability to teach this procedure, never had any complaints filed against him in the many years he's done this procedure, the answer is yes.

Chairman WYDEN. Are you aware of any medical malpractice complaints against Gaul for doing this procedure?

Mr. WALERSTEIN. No, sir.

Chairman WYDEN. Have you ever been contacted by a lawyer, Mr. Walerstein, who wanted to find out where Mr. Gaul, Dr. Gaul, was in order to file suit against him?

Mr. WALERSTEIN. Off hand, I don't think I can remember ever being contacted by an attorney.

Chairman WYDEN. With respect to that $40,000 and the $7,000 that you pay, is it $7,000 per training or $7,000 annually?

Mr. WALERSTEIN. Per client.

Chairman WYDEN. Per training, per each individual training.

[Witness nods affirmatively.]

Chairman WYDEN. Do you give Mr. Gaul travel expenses as well?

Mr. WALERSTEIN. He's an independent contractor. As an independent contractor, he pays his own expenses.

Chairman WYDEN. Let me recognize my colleagues for any questions that they would have.

Mr. MCNULTY. I have no questions, Mr. Chairman.

Chairman WYDEN. The gentleman from Missouri.

Mr. HANCOCK. Just one. Does Dr. Gaul have stock ownership in the corporation?

Mr. WALERSTEIN. No, sir. He's an independent contractor.

Mr. HANCOCK. He could still be an independent contractor and own stock in the corporation.

Mr. WALERSTEIN. Nobody owns—no; he doesn't own any stock in this corporation.

Mr. HANCOCK. Thank you.

Chairman WYDEN. Mr. Walerstein, I must ask whether you brought with you the documents that were subpoenaed from you two months ago.

Mr. BARMAK. Mr. Walerstein has no documents other than those previously produced to the committee, Mr. Chairman.

Chairman WYDEN. I'm sorry, I couldn't hear that last part.

Mr. BARMAK. Mr. Walerstein has with him no documents other than those previously produced to the subcommittee.

Chairman WYDEN. Are there any others that are responsive to the subcommittee's subpoena?

Mr. BARMAK. No documents that we are aware of that are responsive have not either been produced or not produced pursuant to an objection set forth in one of my letters to you.

I would note, too, that so far as I recall, the subpoena requiring Mr. Walerstein's presence today did not require that he bring with him today any documents.

Chairman WYDEN. Will you, Mr. Walerstein, provide an index citing the reasons for your claim of privilege on the documents that weren't supplied today?

Mr. WALERSTEIN. I will discuss it with my attorneys and take it under advisement.

Chairman WYDEN. We will excuse you at this time, Mr. Walerstein, but you remain under subpoena and subject to the recall of the Chair. I think you can see that the Chair and the members of this subcommittee are extremely concerned about what is being done in the area of exodermology and endodermology. As a

Member of Congress from Oregon, I have noted other specific concerns that you have raised when you read the views of Dr. Johnston, the head of the Oregon Board of Medical Examiners. So we will excuse you at this time and want to note specifically for the record that you remain under subpoena and subject to recall. Is there anything further you would like to add?

Mr. BARMAK. Not at this time, other than we have previously offered and renew our offer to produce to the subcommittee documents requested, provided that we have appropriate assurances of confidentiality.

I couldn't help but note, in the course of some of the Chair's comments today, that, at least the inference was drawn by me, that perhaps some confidentiality has been provided to others. I note there was distributed today a document which was produced with the proviso that the name of the producer of the document be kept anonymous. These are the kind of accommodations that I would respectfully suggest are appropriate. Mr. Walerstein has and continues to be willing to cooperate, but is looking for some accommodations on the part of the Chair and this subcommittee.

Chairman WYDEN. The subcommittee remains most interested in cooperating with you, Mr. Walerstein. As the Chair noted in his opening statement, for many, many months the subcommittee has gone to great lengths to try to address these issues, and address these issues in a cooperative way. It was only because that could not be done that the subpoena was issued. So the subcommittee remains most interested in working with you, Mr. Walerstein, in addressing these concerns.

As I mentioned, we would be specifically requesting the reasons why you claim privilege with respect to a number of the specific documents that the subcommittee has asked for.

Unless you have anything further, we will excuse you. Mr. Walerstein, you and your counsel are all excused.

[Mr. Walerstein's statement may be found in the appendix.]

Miss Ordoyne, could you come forward again? Let me note again—and this will be very brief, Miss Ordoyne—you remain under oath. I note the presence of a quorum, with Mr. McNulty and Mr. Hancock.

Miss Ordoyne, do you have any reaction to what you just heard from Mr. Walerstein?

Ms. ORDOYNE. A lot.

I was the business administrator for Dr. Andrew Hegre in 1986, and Walerstein had called me repeatedly, over three or seven times, asking for Dr. Hegre to release more money to him because he had not paid the full $50,000. He did say he was an associate of "Dr." Bennett.

Chairman WYDEN. Which company was he——

Ms. ORDOYNE. World Health Exodermology.

Chairman WYDEN. Any other areas of Mr. Walerstein's testimony today that you would like to address?

Ms. ORDOYNE. I wish you could ask me specifically because now I'm nervous and I don't know.

I do know that——

Chairman WYDEN. When did you first learn the name of Mr. Bennett and Mr. Walerstein?

Ms. ORDOYNE. When they sent brochures to Dr. Hegre, with all the information about World Health. They also stated that they were going to—Now, this wasn't in writing. They did say that they were only going to choose two highly-qualified doctors in the New Orleans area, because it was such a safe and delicate procedure and they didn't want just any doctors to be doing this. But that was not true, either.

Chairman WYDEN. What did Dr. Hegre do after he got the letter from Mr. Walerstein?

Ms. ORDOYNE. He got——

Chairman WYDEN. Let me also note that, with Mr. Walerstein being excused, it is now possible for the cameras and microphones to be turned back on, should the news media desire to do so. Please continue.

Ms. ORDOYNE. Dr. Hegre did get in touch with them, and the procedure over the phone was so inviting, and they said they would pay his way down, which he did go down. He stayed, like I said—I'm sure it was at least a week—when supposedly Dr. Bennett did one or two in front of Dr. Hegre, and then Dr. Hegre was allowed to watch our receptionist have one done.

Chairman WYDEN. Did he go by himself?

Ms. ORDOYNE. Dr. Hegre?

Chairman WYDEN. Yeah.

Ms. ORDOYNE. No; he went with his nurse and with his receptionist. They picked him up in a limousine and brought him to this real plush, three-story building, put him up for a whole week. The $50,000 included—which, by the way, I did not know it was acid. It was supposed to be a mild—it was not supposed to be like an acid peel. It was a mild solution, a safer way to do the procedures that they were going to do.

Chairman WYDEN. Did the nurse have the procedure done on her?

Ms. ORDOYNE. No; just the receptionist of the clinic.

Chairman WYDEN. Who did that procedure?

Ms. ORDOYNE. Supposedly Dr. Bennett, Mr. Bennett.

Chairman WYDEN. What were the results for the receptionist?

Ms. ORDOYNE. What were the results of what, sir?

Chairman WYDEN. Of the procedure done on the receptionist.

Ms. ORDOYNE. It was good.

Chairman WYDEN. Are you any more assured at this point, Miss Ordoyne, after what you've heard from Mr. Walerstein, that this should be a procedure and a service that should be marketed nationwide?

Ms. ORDOYNE. It should definitely be discontinued. Definitely. Please, I'm begging you, that something be done about this. Like I stated before, only qualified dermatologists and plastic surgeons should do this procedure, because they know the depth and they know the strength of the solution and what to use on each patient, whereas this is not being trained and it's not being marketed and told to other physicians.

Chairman WYDEN. You have been very helpful and very patient. Unless any other subcommittee members desire to ask questions, we'll excuse you. Thank you for your patience.

Ms. ORDOYNE. Thank you.

Chairman WYDEN. Before we adjourn, we still have one additional witness.

Pursuant to the subcommittee investigation, it appears that individuals who have either been sold, purchased or trained physicians involved in the franchising of chemical acid peels have been invited as well. Is there an individual in the audience who—Sir, please come forward. We're going to have you identify yourself and take your testimony for the record. The Chair was not aware that you were in the audience.

Dr. GHATNEKAR. I didn't know who to inform, nobody I saw in front, anyone.

Chairman WYDEN. We appreciate——

Dr. GHATNEKAR. So, unfortunately, I couldn't come up and tell anyone.

Chairman WYDEN. Why don't you state your name and spell it, and your legal address, please.

Dr. GHATNEKAR. OK. My name is Jai Ghatnekar. I'm from Pittsburgh, PA.

Chairman WYDEN. Could you spell your name, please?

Dr. GHATNEKAR. G-h-a-t-n-e-k-a-r.

Chairman WYDEN. Your address?

Dr. GHATNEKAR. 4721 McNight Road, which I just changed to 3602 McNight East Drive, Pittsburgh, 15237.

Chairman WYDEN. You are a physician in Pittsburgh?

Dr. GHATNEKAR. Yeah, I'm a general surgeon in Pittsburgh.

Chairman WYDEN. All right. Let me swear you then as a witness. Please raise your right hand.

[Witness sworn.]

ChairmanWYDEN. We will make any prepared comments you would like to make a part of our hearing record in their entirety, and if you care to summarize your principal views, that would be helpful.

TESTIMONY OF JAI GHATNEKAR, M.D., PITTSBURGH, PA.

Dr. GHATNEKAR. Sure. I think I did send you a letter, Congressman. I don't know whether you received it or not. I sent in on FAX a couple of days ago.

Chairman WYDEN. Let me have the staff get a copy of that letter. Why don't you please proceed.

Dr. GHATNEKAR. Shall I read my letter?

Chairman WYDEN. Why don't you, if you would, just summarize your principal concerns in the interest of time. We will examine your letter in detail and make it a part of the record. If you could summarize some of your principal concerns, that would be helpful.

Dr. GHATNEKAR. As far as this issue applies to me, the way I got interested into this is when I went for a course on lyposuction surgery, which I do not practice. I did see what a chemical peel effort can do from international colleagues. Subsequently, a course was being offered. I may have the wrong name, but it was the American Academy of Cosmetic Surgery, in one of the major cities, somewhere in the town, for which I did not go.

I do see in my practice many patients with skin changes. I do operate on them or remove them when I am specifically asked. I

can help my patients who have more than one specific lesion, but I am required to ask to remove those lesions. That's how I got interested, got into this.

After I got interested into this, I did get a letter from Mr. Walerstein. I didn't initially pursue that for some time, but when I saw the flier coming from the American Academy of Cosmetic Surgery—I may be wrong on that—I thought this is something which is not very uncommon, or probably uncommon in the way that most of the physicians are not aware of it. Also, the general population at large is probably not aware of it.

So the marketing material that Mr. Walerstein's company has sent I thought will help the people to become aware that there is a technology like this does exist. Now, I had residency training for six years, and not even once, as far as I remember, did I see any of this in the hospital.

Subsequently, after researching this to some extent, which the research is limited to very few articles that I could find in my hospital library, I thought this may not be a bad idea. I'm not again going by the statistics that Mr. Walerstein's company gave. I knew that this is very high statistics and I'm not again after every patient who walks in my door to go after this.

Subsequently, I did find a book in the hospital library which just came after I had gotten involved in this. This is by two plastic surgeons, which I have brought from the hospital, from the library. Both of them are from Florida. They have been involved with this procedure for 25 years, as was stated in the book. In their hands, they learn again the procedure from lay people. They did not get the information from the lay people but they eventually modified the techniques and they came to a technique they think is perfect for their patients. According to the book, even though I know the professor of toxicology has given his opinion, according to the book here, what the surgeons say, the effects absorbed by the chemical on the body as such are "very minimal", quote/unquote, according to the book.

I did do a very few cases and the results were excellent. Again, in my specific practice, I have a crash cart in my office. I have a cardiologist standing by, which is my wife. I am a surgeon by myself. I see the patients in the hospital every day, twice a day, three times a day. The same thing I apply to this particular person if I do any procedures.

So as far as I'm concerned, I am following exactly like a patient had surgery. The results were marvelous to patients, better for me. Again, the results are subjective, and objective, too. The patient may feel a change amongst them maybe 5 years, 10 years, 20 years, but it's the self-esteem which increases afterwards that change is definitely seen. As I have mentioned in my letter, one of the twin sisters said that she definitely looks better than her sister now.

One of the local real estate salesperson, his career zoomed. He has a wife which looks much younger than him, and he wanted to be a match for her. According to his wife, his appearance improved, performance improved, and its remarkable what a successful career he has.

Again, I'm a trained person because I operate every day. I know how to take care of patients in the operating room. I have the same

technology available in my office. I do exactly the same thing if I would take the patient to the operating room and operate. Nowadays we send the patients from the operating room straight home after they go for outpatient surgery, which we do all the time, with the medications given, including general anesthesia, spinal anesthesia, regional anesthesia and no anesthesia. We do all that all the time.

So as far as I'm concerned, I follow the basic principles of surgery. In my hands, so far, I've had good results. Again, pain is a subjective thing. A person which I see all the time in my practice, a person having the same surgery and the same surgery for another person, the amount of pain that person gets is entirely different. It depends upon the particular person.

Unfortunately, we cannot judge a patient's pain. I don't have a thermometer to judge a patient's pain. But I'm sure the pain is perceived by a patient at their own perceptions. I think one of the patients who had the procedure performed, she did say she had excruciating pain, and I totally believe her, because that's what she felt. I don't send my patients home. I admit them to a nursing home. I watch them and observe them. So I think when you follow the principles of surgery, or when you follow the basic medical knowledge, the procedure is safe and which I can say our evidence is in the book here, which is by two plastic surgeons from Florida.

[The letter referred to above may be found in the appendix.]

Chairman WYDEN. Let me ask you a couple of questions. Is your program in Pittsburgh called "New Faces of Pittsburgh"?

Dr. GHATNEKAR. That's correct.

Chairman WYDEN. I understood you to say there have been no complaints that have been filed against you and all your patients are very satisfied?

Dr. GHATNEKAR. As far as to the best of my knowledge, the patients that I did, nobody had filed any complaint against me.

Chairman WYDEN. I have here, in the Court of Civil Pleas in Allegheny County, PA, Civil Division, Commonwealth of Pennsylvania, Dorothy Steffler and Jerry Steffler, husband/plaintiffs, versus—and excuse my bad manners; I can't pronounce your name.

Dr. GHATNEKAR. No problem.

Chairman WYDEN. Against you individually, and doing business as New Faces of Pittsburgh, John Gaul, Medical Marketing Services, Inc.

Dr. GHATNEKAR. They have not filed any complaint yet. There are no charges as far as I know of as of today.

Chairman WYDEN. It says you were notified that Dorothy Steffler and Jerry——

Dr. GHATNEKAR. Yes; but that does not mean a complaint has been filed.

Chairman WYDEN. It says they commenced an action, a civil action, against which you're required to defend, January 17, 1989. That doesn't exactly square with what you told me, that everyone was satisfied.

Dr. GHATNEKAR. No; as far as I can say, Congressman, they have just filed an intent for a complaint, but they have not filed the papers yet, as far as I'm aware of. I have not seen any complaint yet.

Chairman WYDEN. But your view is that this is a satisfied patient, too?

Dr. GHATNEKAR. She has not filed, so I really cannot comment on that.

Chairman WYDEN. OK.

Let me ask you just one other question, and then I will recognize my two other colleagues. Did Mr. Gaul train you as well?

Dr. GHATNEKAR. Yes, sir.

Chairman WYDEN. OK. You mentioned that the marketing that Mr. Walerstein does is helpful to patients. How does the marketing material that Mr. Walerstein puts out help patients make intelligent choices with respect to cosmetic surgery?

Dr. GHATNEKAR. No; patients don't make an intelligent choice.

Chairman WYDEN. Patients don't make intelligent choices?

Dr. GHATNEKAR. No; they just see the advertisement and then they did come to the office. I told them in layman's language what it can do, and if they want what they're specifically looking for, what they really want, and many patients do not want anything done.

Chairman WYDEN. So you say patients don't make good medical choices.

Dr. GHATNEKAR. No; I didn't say that.

Chairman WYDEN. Sure, you did. You said they can't make intelligent medical choices.

Dr. GHATNEKAR. No, no. I didn't say that—I didn't mean that, then.

Chairman WYDEN. OK. We'll ask it again.

Patients can't make intelligent——

Dr. GHATNEKAR. No; sure they do. All my patients were extremely intelligent patients.

Chairman WYDEN. Just one last one. Did Mr. Gaul train you in Pittsburgh?

Dr. GHATNEKAR. That's correct.

Chairman WYDEN. Do you advertise?

Dr. GHATNEKAR. I haven't done that for some time because the cost involved is exorbitant, which I didn't know before.

Chairman WYDEN. Just for the record, could you give the subcommittee some of the previous advertisements that you have done for——

Dr. GHATNEKAR. You have one right there.

Chairman WYDEN. All right. Let me recognize my colleagues for any questions.

Mr. MCNULTY. I have no questions, Mr. Chairman.

Chairman WYDEN. Any from the gentleman from Missouri?

Mr. HANCOCK. No, Mr. Chairman.

Chairman WYDEN. I said I had one last question I think a couple ones ago. Let me ask one other question with respect to Mr. Walerstein.

With respect to your discussions with Mr. Walerstein, did you discuss safety issues and profit issues?

Dr. GHATNEKAR. I did not discuss profit issues at all. As far as safety issues is concerned, he's—really, the safety issue was discussed by Dr. Gaul and not really by him.

Chairman WYDEN. What did your discussions with Mr. Walerstein focus on?

Dr. GHATNEKAR. Regarding the procedure. He told me what the procedure does, what the procedure does to the patient. That's what he told me, nothing more than that.

Chairman WYDEN. Mr. Walerstein told you then about the procedures and how they worked?

Dr. GHATNEKAR. He give me just a rundown about what the procedure is.

Chairman WYDEN. How it worked?

Dr. GHATNEKAR. Because his wife had the procedure done. That's what he said.

Chairman WYDEN. What was your understanding of the relationship between Mr. Gaul and Mr. Walerstein?

Dr. GHATNEKAR. As for Mr. Walerstein, Dr. Gaul, or Mr. Gaul, works for him as a medical consultant.

Chairman WYDEN. If my colleagues at this point still have no questions——

Mr. HANCOCK. I have a couple.

Chairman WYDEN. I would be happy to recognize the gentleman from Missouri.

Mr. HANCOCK. Thank you, Mr. Chairman. Just a couple of questions.

I understand that you were trained or received this training from the World Health Research Center?

Dr. GHATNEKAR. No; endodermology—Medical Marketing Services.

Mr. HANCOCK. What's the name of it?

Dr. GHATNEKAR. Medical Marketing Services.

Mr. HANCOCK. Now, that is Mr. Walerstein's company. I understand there is all the way from a $35,000 to $50,000 fee, someplace in there, that you pay up front on a contract basis. What does that fee include?

Dr. GHATNEKAR. As far as I could understand, basically for marketing support, to provide the ads and have the person come over——

Mr. HANCOCK. Anything else?

Dr. GHATNEKAR. Also, for a year he will provide different types of ads.

Mr. HANCOCK. This was primarily a merchandising program rather than a training program; is that correct? I mean, an educational type program. His services are primarily a merchandising program?

Dr. GHATNEKAR. Mr. Walerstein's service?

Mr. HANCOCK. Yes.

Dr. GHATNEKAR. Yes; I would say.

Mr. HANCOCK. After this initial program, do you continue to have any further financial obligation?

Dr. GHATNEKAR. No.

Mr. HANCOCK. In other words, it's a flat fee and then that's it?

Dr. GHATNEKAR. That's right.

Mr. HANCOCK. What about the printing of brochures and things like that?

Dr. GHATNEKAR. They were included in the package.

Mr. HANCOCK. Included in the $50,000. In other words, you don't pay him any more money?

Dr. GHATNEKAR. No.

Mr. HANCOCK. This fee you paid to them is not for training in the treatment?

Dr. GHATNEKAR. I think it's all-inclusive.

Mr. HANCOCK. But it does include medical training?

Dr. GHATNEKAR. That's correct.

Mr. HANCOCK. OK, and that training was provided by Mr. Walderstein or Dr. Gailt?

Dr. GHATNEKAR. But I did not know what was the relation between Mr. Walerstein and Dr. Gaul. Whether they had an official relationship, I have no idea.

Mr. HANCOCK. I understand.

How much time did Dr. Gaul spend with you?

Dr. GHATNEKAR. He was—He came on the day before they did the procedure and then he showed the procedure. I did one procedure and then he removed the mask. He showed me how to remove the mask and watch how you apply the powder on the face. That's what he did.

Mr. HANCOCK. Two treatments?

Dr. GHATNEKAR. That's correct.

Mr. HANCOCK. That sounds limited.

Dr. GHATNEKAR. Can I say something?

Mr. HANCOCK. Yes.

Dr. GHATNEKAR. As a surgeon, we see new technology coming in every day. Usually, when something is new, we don't have time to go through the residency again, which we don't do that. We usually see one or read one and do one. That's what we do. That is true in any business.

I just had a person in my office yesterday trying to fix up a chair, and he's a handyman. He says he has done all sorts of jobs where he could not fix the chair, so he said I'm going to fix that chair, so that I know how I'm going to do it the next time.

Mr. HANCOCK. Did Mr. Gaul demonstrate this procedure on a live patient of yours, or was it a model of some type?

Dr. GHATNEKAR. No; he demonstrated the procedure.

Mr. HANCOCK. It was a patient, though, that came to your offices for the treatment?

Dr. GHATNEKAR. That's correct.

Mr. HANCOCK. Where did this patient come from? Was it an employee?

Dr. GHATNEKAR. I would say the lady who had the procedure done first was subsequently a consultant for the procedure.

Mr. HANCOCK. I beg your pardon?

Dr. GHATNEKAR. The lady who had the procedure done, she subsequently worked as a consultant for me.

Mr. HANCOCK. Where did she come from? Who produced her? Where was the contact made for her to come in for this procedure?

Dr. GHATNEKAR. I did advertise to look for a person who would like to work——

Mr. HANCOCK. But she was not contacted or obtained by Mr. Walerstein or Mr. Gaul?

Dr. GHATNEKAR. No.

Mr. HANCOCK. OK.

Chairman WYDEN. Let me pick up on the gentleman's questions. The woman who had the procedure done became a consultant, is that correct?

Dr. GHATNEKAR. To do the experience that she has gone through.

Chairman WYDEN. Is that the same person as the one who filed the lawsuit?

Dr. GHATNEKAR. Yes.

Chairman WYDEN. Did you do the procedure or did John Gaul do the procedure?

Dr. GHATNEKAR. Mr. Gaul, John Gaul, did the procedure. He demonstrated to me how to do the procedure.

Chairman WYDEN. So he was practicing medicine in the State of Pennsylvania without a license then, was he not, in your office?

Dr. GHATNEKAR. I think that's what happened. I have to be honest on that.

Chairman WYDEN. Were you aware of that?

Dr. GHATNEKAR. It didn't come to mind at the time.

Chairman WYDEN. What do you think about that now?

Dr. GHATNEKAR. He did.

Chairman WYDEN. Have you talked to the Pennsylvania authorities about it?

Dr. GHATNEKAR. No; I have not.

Chairman WYDEN. Do you plan to?

Dr. GHATNEKAR. I think I should.

Chairman WYDEN. I think so, too. Like when we get done with the hearing.

Mr. HANCOCK. Would the chairman yield.

Chairman WYDEN. I will be happy to yield to my colleague.

Mr. HANCOCK. Do you have any idea of how many doctors in your State were involved in this program?

Dr. GHATNEKAR. There's one in Pittsburgh itself. He's an obstetrician/gynecologist. I do see his ads quite often. There is one close to Pittsburgh, and I think there is one in the eastern part of Pennsylvania. There may be more which I'm not aware of.

Mr. HANCOCK. Did Mr. Walerstein give you any indication of how many of these programs he may set up nationwide?

Dr. GHATNEKAR. No; I have no idea.

Mr. HANCOCK. I don't have any further questions. Thank you, Mr. Chairman.

Chairman WYDEN. Let me thank my colleague from Missouri, my colleague from New York, both of whom have been very, very patient on an extremely busy day.

Does staff have any additional questions, minority or majority staff? If not, Doctor, we thank you. We hope that you will follow up on that matter of contacting the Pennsylvania State authorities immediately. Unless you would like to add anything further, the subcommittee is adjourned.

Dr. GHATNEKAR. I have nothing more to add.

Chairman WYDEN. We are adjourned.

[Whereupon, at 3:23 p.m., the subcommittee was adjourned subject to the call of the Chair.]

APPENDIX

MAJORITY MEMBERS
RON WYDEN, OREGON
CHAIRMAN

ELIOT L. ENGEL, NEW YORK
NORMAN SISISKY, VIRGINIA
JIM OLIN, VIRGINIA
MICHAEL R. MCNULTY, NEW YORK

101st Congress

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
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MINORITY SUBCOMMITTEE PROFESSIONAL
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OPENING STATEMENT

THE HONORABLE RON WYDEN

CHAIRMAN

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

SEPTEMBER 21, 1989

The Subcommittee on Regulation, Business Opportunities & Energy of the House Small Business Committee, pursuant to Rules X and XI of the U. S. House of Representatives, is conducting an investigation into the cosmetic surgery and procedures industry. To date, the subcommittee has held three public hearings to assess this industry, which is one of this country's fastest growing small businesses.

This investigation is an important part of this subcommittee's efforts to exercise the oversight resopnsibilities conferred upon it by the full committee pursuant to Rule XI of the Rules of the Committee on Small Business. Rule XI requires us to exercise oversight as to all of the regulation and business opportunities of small businesses, including the regulatory policies of Federal departments and agencies, and to continually evaluate the need for corrective legislation in these areas.

The cosmetic surgery and procedures industry investigation is the latest in a series of investigations initiated by the subcommittee to assess changes in how medical care is delivered, how the medical profession is being policed, and whether the quality of health care is negatively affected. We have found that medicine is emerging as a booming business. Medicine, however, is largely unregulated, unlike virtually every other industry where the government has programs to protect consumers from fraud and unsafe products.

Over the last two years, this subcommittee has investigated many trends in the medical field and how they are affecting physicians as businessmen and the quality and cost of health care. No trend is more pronounced and widespread than that of the growing number of doctors operating outside the hospital setting. Although the subcommittee has found that most in the medical community are honest and ethical, many are not. Whether it be consumers

counting on safe, reliable medical testing, infertile couples seeking to have a baby or those hoping to improve their appearance through cosmetic surgery or procedures -- all are highly susceptible to potential exploitation.

The common thread through all the subcommittee's investigations has been (1) inappropriate use and lack of credentials, (2) misuse of medical technologies, (3) no minimum standards for outpatient facilities and (4) false or misleading advertising. Unfortunately, we also have found that the government has either been oblivious to these alarming trends or has chosen to ignore them. Our federal watchdogs have abdicated their responsibility, the quality of health care has deteriorated and American consumres have been left to fend for themselves.

Indeed, Food & Drug Administration Commissioner Frank Young told this subcommittee that medical fraud costs American consumers as much as $40 billion each year.

No where are these trends more evident than in the burgeoning cosmetic surgery and procedures industry.

The subcommittee's investigation has found that in many cases cosmetic surgery and procedures are being performed by unqualified doctors and in many cases in totally inadequate facilities. Medical advertising -- sometimes misleading and often blatantly false and deceptive -- is rampant. Countless ads across the country claim that these procedures are safe, easy and painless. And since they are done in the doctors' offices in fully 95% of the cases, consumers are inclined to believe those claims. Consumers are left unable to tell the good doctor from the bad.

Consequently, hundreds of thousands of American consumers are being lured into doctors' offices with the promise that these procedures will reshape not only their bodies, but their very lives. Both are true, but far too often disastrously so.

The subcommittee is particularly concerned that consumers are being inundated with some doctors' false and deceptive advertising. Those ads prey on their insecurities, prompting them to have potentially dangerous, costly and unnecessary cosmetic surgery and procedures. Additionally, we are concerned that many potentially unqualified physicians are tempted to perform procedures for which they have little or no training because they see promised dramatically increased profits.

Beyond the watchful eye of hospital review committees, insurance company audits and government review, the doctor himself is left to decide whether he is qualified, where he can do them and on whom.

Late this winter, consumers, doctors, lawyers and government regulators brought to the subcommittee's attention the national marketing campaign of Mr. Michael Walerstein and various of his cosmetic surgery and procedures business entities. Indeed, the American Society for Plastic and Reconstructive Surgery and the American Academy of Dermatology have filed formal complaints with the Federal Trade Commission against Mr. Walerstein. Given the subcommittee's efforts to assess the role of medical advertising in fueling the unprecedented growth of this medical field, what the effect on competition in the medical industry may be and what the possible public health risks may be, such a marketing and training enterprise is of particular relevance to this subcommittee's investigation. The subcommittee is also striving to obtain the clearest possible picture of the financial operation of these types of small businesses -- how and where they get their profits, and how they really operate -- in order to accurately assess these operations.

Since the subcommittee first began its investigation into these franchising operations, we have received letters and phone calls from doctors, patients, lawyers and regulators coast-to-coast, describing deaths and disfigurement at the hands of Mr. Walerstein's disciples.

Despite Mr. Walerstein's refusal to cooperate with the subcommittee, beginning with the staff's first encounter with him in April 14, 1989, some details of his enterprise have been unearthed. Mr. Walerstein's national advertising company offers franchised chemical peels. For a reputed $45,000 to $50,000, his physician clients receive training in how to do the chemical peel and how to market the procedure to patients. The lure to the doctors is that they can enhance their income from $100,000 to $400,000 each year. The lure to patients is that the process supposedly "turns back the clock of time 10 to 20 years and more."

The chemical peel procedure typically involves the application of acid to the face, wrapping the face in tape for 48 hours to force the acid to eat deeper into the layers of skin, remaining in a darkened room for one week and forever protecting the face from sun exposure.

Mr. Walerstein's "Dear Doctor" solicitation letter tells doctors that, "your patient will be left with NEW FRESH TIGHT SKIN THAT HAS THE TRUE [illegible] GLOW." He further reminds doctors that, "this is new, fre[illegible] glowing skin -- not the stretching of old, tired skin, and offers a viable alternative to the associated risks of some surgical procedures."

To the contrary, however, the father of the chemical peel -- Dr. Thomas J. Baker, cautions that this "controlled burn" should not be taken lightly merely because it is not, technically speaking, an operation. Dr. Baker has written that the toxic effects of the acid itself can cause muscular weakness, faintness, weak and irregular pulse, depressed respiration, constricted pupils, coma, and possibly death. Other physicians have reported disfigurement, severe infections, near blindness, and constant pain. Indeed, in the hands of an untrained physician, this procedure amounts to a deadly weapon disguised as a "non-surgical procedure."

But Mr. Walerstein's sales pitch to physicians departs dramatically from those warnings. Specifically, he promises physicians that his "exclusive method," "offers a viable alternative to the associated risks of some surgical procedures." He describes his technique as, "our SAFE proven system."

Indeed, Mr. Walerstein's sales packages employ many of the elements of advertising that raised serious concerns at the subcommittee's previous hearings. Mounting reports of injuries and deaths raise red flags about the qualifications of doctors, how, by whom and where they are trained, where they are performing the procedures, and how their ads are deceiving patients about the risks associated with the procedures.

Pursuing the investigation without the crucial documents requested from Mr. Walerstein, it appears that many physicians and patients nationwide are buying into his promises. It appears, further, that some of those to whom franchising operations are sold are then undercutting Mr. Walerstein by establishing themselves as "spin-offs," offering franchises themselves through interstate advertising.

We have continually tried to solicit Mr. Walerstein's voluntary cooperation with the subcommittee's important investigation. Mr. Walerstein and his representatives have repeatedly refused to cooperate. Following his refusal to appear voluntarily before the subcommittee in May, the subcommittee reluctantly subpoenaed documents from Mr. Walerstein and his acid peel franchising enterprises.

In the ensuing months, we have witnessed Mr. Walerstein's successful thwarting of the service of subpoenas upon him; continous legal bickering and vague objections to the subcommittee's subpoenas and indeed to the subcommittee's investigation itself; eleventh-hour responses to virtually every request from the Chair; and to date the production of nothing but a token number of documents to the subcommittee.

Mr. Walerstein's and his representatives continued efforts to stall the subcommittee investigation, however, have not been entirely successful. Subsequent research revealed that Mr. Walerstein's ventures have had prior brushes with government investigators. He has been investigated by Florida state authorities for practicing medicine without a license. He also has an established history of evading investigators.

Thus far, without Mr. Walerstein's assistance, the subcommittee has been unable to find even one licensed physician who trains Mr. Walerstein's physician clients to do acid face peels. In fact, all three of Mr. Walerstein's known associates who have trained clients for him have been cited for practicing medicine without a license. So-called "Dr." Ronald Bennett, we are informed, has been run out of both California and Florida for practicing without a medical license. Mr. Theodore Levchenko -- who is also known as Mr. Chris Hall, or by some five other aliases -- is currently incarcerated on federal weapons charges. And Mr. John Gaul was a doctor whose license was revoked in Florida after he was found to be selling drugs to undercover hookers.

For that reason, I as Chair called the subcommittee together today. Mr. Walerstein was directed to appear personally to produce the documents that are under subpoena. It was my hope and expectation that this subcommittee would finally receive the necessary materials that we subpoenaed over two months ago. At the very least, I expected that we would finally and for the first time receive some concrete and specific explanations as to why the documents have not been produced. Unfortunately, and to my great regret, in yet another example of Mr. Walerstein's eleventh-hour stalling tactics, I received the following letter at about 4:00 yesterday afternoon.

Since I think its uncooperative and disrespectful tone speaks for itself, I will read the letter into the record.

Obviously, Mr. Walerstein has chosen to disobey this subcommittee's instructions. He appears to believe that he is above the committee and above the law. By refusing to appear to justify and explain his noncompliance, he has shown disrespect for this subcommittee and for the House as an institution.

The claim that Mr. Walerstein already produced everything necessary is particularly bizarre in view of the fact that Mr. Walerstein's lawyers have written me twice saying that there were additional documents that they would make available to the subcommittee if their conditions were met, and at the appropriate time.

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Mr. Walerstein has made it impossible for this subcommittee to give him a hearing on his purported objections. This is particularly surprising and ironic in view of the fact that as recently as last week, his attorney was demanding an opportunity to meet with me. It appears that Mr. Walerstein fears the public forum.

The Chair has reviewed the exchange of correspondence over the last six months referred to in the most recent letter from Mr. Walerstein's attorneys, and has found the so-called objections contained in it to be completely inadequate.

These so-called objections consist of nothing but three or four sentences of vague legal labels, such as "constitutional rights," without any factual or legal argument to back them up. Worse yet, the so-called objections change from one day to the next. One minute, they claim the problem is self-incrimination, the next minute they say their main concern is "trade secrets" and then the minute after that they are back to referring to the "potential" applicability of self-incrimination claims. Mr. Walerstein and his lawyers have been told repeatedly that if they want to present objections, and have them taken seriously, they have to come forward with something concrete and specific. They never have.

This subcommittee has been more than lenient and fair to Mr. Walerstein and has given him every possible opportunity to set forth a persuasive case for his failure to comply. Mr. Walerstein has been advised repeatedly as to how to present his Fifth Amendment claim if he wants to assert it. This subcommittee has always been willing and continues to be willing to receive serious, good faith objections from Mr. Walerstein or his representatives. Unfortunately, neither he nor his representatives have made any.

Therefore, as Chairman, I find the objections presented so far to be totally inadequate. Nothing in any of the correspondence to date persuades me that Mr. Walerstein and his company Medical Marketing Services, have any valid legal basis for resisting these subpoenas. Most of the objections, in fact, are completely frivolous. Nothing in any letter from Mr. Barmak, and certainly nothing in this most recent eleventh-hour letter, gives me any reason to reconsider that position.

Accordingly, as Chair, I hereby reject [illegible] all objections presented by Mr. Walerstein and [illegible]ical Marketing Services, and I direct compliance with all categories of both subpoenaes forthwith.

The subcommittee will meet in the near future to consider the appropriate actions should Mr. Walerstein continue in his present course of action.

ANNE DEUTSCH
FORT-LAUDERDALE, FLORIDA

STATEMENT BEFORE

THE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

NOVEMBER 2, 1989

MR. CHAIRMAN, THANK YOU FOR ASKING ME TO BE HERE.

I HAD A CHEMICAL FACE PEEL IN MARCH, 1988, AND MY LIFE HAS NOT BEEN THE SAME SINCE.

WHEN I WENT IN TO HAVE THE ACID PEEL DONE, I WAS A HEALTHY 67 YEAR OLD WHO WORKS WITH YOUNGER PEOPLE, FEELS YOUNGER THAN MY AGE AND WANTED TO LOOK YOUNGER TOO. IN OTHER WORDS, I SUFFERED A FEMALE AILMENT KNOWN AS VANITY.

BUT WHEN I CAME OUT, I WAS NEARLY BLIND. AFTER WEEKS OF TESTS--ESCRUCIATINGLY PAINFUL TESTS WITH NEEDLES PUT IN MY EYES TO TEST THE PRESSURE AND SCAPLES TO SCRAPE TISSUE FROM MY EYES TO DETERMINE THE NATURE AND EXTENT OF THE DAMAGE -- I WAS TOLD THE RESULT.

I HAVE PERMANENT DOUBLE VISION, DAMAGED CORNEAS AND EXTREME SENSITIVITY TO GLARE THAT OFTEN MAKES IT TOO PAINFUL FOR ME [illegible]E OUTDOORS IN THE SUNLIGHT AND EVEN TO STAND THE GLARE OF ANY LIGHTS AT NIGHT. I WILL REQUIRE CARE FROM AN OPTHALMOLOGIST FOR THE REST OF MY LIFE.

I TAKE STEROIDS TO TRY TO CONTROL THE INFLAMMATION IN MY EYES. BUT THE STEROIDS GIVE ME A MUCH GREATER CHANCE OF DEVELOPING GLAUCOMA -- WHICH COULD LEAVE ME COMPLETELY BLIND.

THIS ALL HAPPENED TO ME BECAUSE I WAS VAIN. IT HAPPENED BECAUSE I BELIEVED WHAT A DOCTOR TOLD ME. DR. WACHTEL HAD DONE SURGERY ON MY DAUGHTER FIFTEEN YEARS AGO AND HE'D DONE A GOOD JOB, SO I TRUSTED HIM. IT HAPPENED BECAUSE DR. WACHTEL DIDN'T KNOW WHAT HE WAS DOING. HE DECIDED TO LAUNCH A NEW MEDICAL CAREER WELL BEYOND HIS TRAINING IN OBSTETRICS AND GYNECOLOGY, BUT I FELT I KNEW HIM AND I TRUSTED HIM. IT HAPPENED BECAUSE I BELIEVED ADS LIKE THIS ONE -- "INVITATION TO A YOUNGER FACE" AND ALL OF THAT "WITHOUT SURGERY".

AND MOST IMPORTANTLY, I'M NEARLY BLIND TODAY BECAUSE PEOPLE LIKE ME ARE AT THE MERCY OF THE MEDICAL COMMUNITY. THEY WON'T STOP A DOCTOR FROM DOING THINGS THAT HE'S NOT QUALIFIED TO DO. THEY ALL SEEM TO PROTECT EACH OTHER -- NOT THEIR PATIENTS.

AND THE GOVERNMENT JUST LETS IT HAPPEN. THEY LET DOCTORS DECIDE WHAT THEY ARE AND ARE NOT QUALIFIED TO DO, WHERE THEY CAN DO IT AND WHO THEY CAN DO IT TO. THEY LET THESE ADS RUN ALL OVER THE COUNTRY -- ADS THAT CONFUSE AND MISLEAD EVEN THE MOST SKEPTICAL

PEOPLE. WE ALL WANT TO LOOK YOUNGER, TO FEEL BETTER ABOUT OURSELVES. AND THESE ADS TELL US THAT WE CAN DO JUST THAT--VIRTUALLY WITHOUT RISK. ACCORDING TO THE ADS, THESE PROCEDURES ARE PAINLESS, AND THEY'RE SO SAFE THAT THEY CAN EVEN BE DONE IN THE DOCTOR'S OFFICE.

THERE'S NO WAY FOR ANY OF US TO FIND WHETHER WE'RE TOLD THE TRUTH OR A LIE. WE DON'T KNOW IF THE DOCTOR IS GOOD OR BAD, IF HE'S BEEN WELL TRAINED TO DO THE PROCEDURE OR NOT, OR IF HE'LL KNOW WHAT TO DO IF COMPLICATIONS COME UP.

THE SYSTEM IS FAILING US AND WE HAVE NOWHERE TO TURN.

WHEN I LOOK BACK ON HOW I GOT INTO THIS, I FEEL ANGRY AND TAKEN. AFTER SEEING ONE OF THESE ADS, A FRIEND OF MINE WAS CURIOUS AND SHE ASKED ME TO GO WITH HER TO ONE OF DR. WACHTEL'S "SEMINAR PARTIES". WE WERE SUPPOSED TO LEARN ALL ABOUT "NON-SURGICAL FACIAL REJUVENATION" THAT COULD "ERASE WRINKLES AND YEARS" FROM THE FACE.

THE "SEMINAR" SEEMED A LOT LIKE A TUPPERWARE PARTY -- WINE AND CHEESE, GAMES AND EVEN DOOR PRIZES. THE DOOR PRIZES WERE DISCOUNTS ON CHEMICAL PEELS. THERE WERE ALSO "MODELS" WHO WERE SUPPOSEDLY SATISFIED PATIENTS OF DR. WACHTEL'S. FOR ALL I KNOW, THEY MAY HAVE BEEN SHILLS, THOUGH, GIVEN WHAT HAPPENED TO ME.

THERE'S NOT REALLY MUCH TO TELL ABOUT THE ACTUAL PROCEDURE ITSELF. I DIDN'T KNOW THERE WAS A PROBLEM AT THE TIME, I WAS IN VERY LITTLE PAIN DURING MY EIGHT DAYS RECUPERATING IN THE NURSING HOME AND UNTIL FOUR OR FIVE DAYS AFTER THE ACID PEEL, I THOUGHT EVERYTHING WAS FINE.

BUT WHEN I GOT HOME, I REALIZED IMMEDIATELY THAT MY VISION WAS VERY FUZZY. MY LITTLE HALF-GLASSES -- USUALLY WORN FOR READING LIKE MOST 60 YEAR OLDS -- DIDN'T HELP. I WENT BACK TO DR. WACHTEL AND HE KNEW SOMETHING WAS WRONG AND HE SENT ME TO A LOCAL OPAHALMOLOGIST. WHEN HE FELT HE WAS UNABLE TO TREAT MY CONDITION, HE SENT ME TO THE BASCOM-PALMER EYE INSTITUTE. THE FIRST THING THE CORNEA SPECIALIST ASKED ME WAS, "WHY DID YOU PUT CROTON OIL ON YOUR FACE"?

IN CASE YOU DON'T KNOW, THE ACID PEEL THAT DR. WACHTEL USES IS MAINLY PHENOL ACID WITH A FEW DROPS OF CROTON OIL. THE CROTON OIL AND THE PHENOL INTERACT, MAKING THE SOLUTION EAT DEEPER INTO THE SKIN.

I'VE LEARNED TO LIVE WITH DOUBLE VISION. AND I'VE LEARNED TO LIVE WITH THE FACT THAT IT'S TOUGHER FOR ME TO DO MY JOB, TOUGHER FOR ME TO DRIVE AND TOUGHER FOR ME TO GET OUT AT NIGHT AT ALL. KNOWING WHAT I KNOW NOW, I'M JUST GLAD TO BE ALIVE AND COMPLETELY BLIND.

AND IF THERE'S ANYTHING I CAN DO TO WARN OTHER PEOPLE ABOUT WHAT CAN HAPPEN TO THEM, I WANT TO DO IT. I'M CONVINCED THAT NEITHER MY GOVERNMENT NOR THE MEDICAL COMMUNITY IS GOING TO DO THE JOB.

THANK YOU AGAIN FOR ASKING ME TO TELL MY STORY.

BRENDA ORDOYNE
GRETNA, LOUISIANA

THE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

NOVEMBER 2, 1989

Mr. Chairman, thank you for caring enough to try to protect me and others like me from doctors who don't know what they're doing and from others who don't seem to care what happens to us. I'm here today because I don't want anyone else to go through what my family and I did.

Four years ago this December, I had a chemical face peel. I didn't have it done to make me look younger -- I had it done to correct a scar on my right cheek. I've had that scar since I was thirteen, when a mole was removed to prevent it from becoming a melanoma. And I had the acid peel done by a doctor I respected, admired and for whom I had worked for nearly 14 years.

Since I had worked for physicians for so many years, I thought I was a cautious and thoughtful patient. I thought I knew what questions to ask to protect myself. But I found out that I was wrong.

Dr. Andrew Hegre told me that the chemical peel was safe and easy -- a piece of cake. But what I got was the most painful, frightening experience of my life.

Today I have more scars than before the procedure, my eyes -- my corneas specifically -- are permanently damaged, leaving me with blurred vision, tremendous sensitivity to light, and more chances of developing cataracts, and ongoing doses of steroids and other drugs that themselves can cause serious side effects.

Looking back now, I don't know how I could have been so stupid. But I asked my doctor whether there could be complications, I asked him if I could be allergic to the chemicals. But Dr. Hegre allayed all my fears.

Even though I knew that Dr. Hegre had bought the chemical peel package because he was looking for a fast way to make more money, I had faith in him. And even though I knew that he had only seen a couple of the face peels done and had only done eight or so himself, I had faith in him. I should explain that Dr. Hegre is an internist and allergist. He had an excellent reputation in the New Orleans area and was thought to be a brilliant diagnostician.

Despite everything that has happened -- three months of excruciating pain, fear that the open wounds all over my face would never heal, the threat of surgery on my eyes to correct the damage to my eyelids, and even the worry that I would never be emotionally or physically normal again -- I still can't really blame Dr. Hegre.

I believe that Dr. Hegre was just as surprised by what happened to me as I was. I don't think that he really knew what the complications could be. I don't think he knew how to watch for "danger signs". And I don't think he knew what to do about them once they actually showed up.

I think that Dr. Hegre believed what he was told by Michael Walerstein -- the man in Florida who sold him the chemical peel package -- and by Ronald Bennett who showed him supposedly how to do the face peel correctly. I think that Dr. Hegre really did believe that the peel was a quick, safe way to make money.

As the Administrator in Dr. Hegre's office, I saw the material that Mr. Walerstein sent him. And I firmly believe that as long as advertising like that goes out to doctors -- and then they pass it along to patients -- more people will be hurt and more people will even be killed.

I'd like to tell you just briefly what happened to me from the time I first decided to have the acid peel done, to the time when I began to find out just how many things had gone wrong, how seriously I'd been hurt.

After Dr. Hegre came back from three or four days of watching Mr. Bennett perform several face peels in Florida -- one on our receptionist -- he did several patients who looked really quite good. I decided to ask him what the peel could do for the scar on my right cheek. It had never really bothered me that much until Dr. Hegre began to say, pretty frequently, "why don't you let me take care of that for you." Then, I must confess that I became a little self-conscious about it.

I'd never wanted to try to correct it because it didn't worry me enough to actually have <u>surgery</u>. But the chemical peel was different, or so I was told. It wasn't "real" surgery with all the attendant risks and complications, it didn't require general anesthetic, and I didn't have to go the hospital to have it done. It seemed the perfect solution.

As I said earlier, I asked Dr. Hegre about the possible complications from the peel. He told me that <u>no</u> procedure was without risk, but that the peel was virtually foolproof. When I asked him about the possible risks from infection, he told me that he wouldn't even have to give me antibiotics after the procedure. When I asked him whether I might be allergic to the

chemicals, he told me that there was no chance since the acid removed only one layer of skin and that, in any case, the powder that's applied several days after the acid peel would block any allergic reaction.

In fact, Dr. Hegre told me that the procedure was so easy and that I would heal so quickly, that in six days I would just look like I'd been in the sun for twenty minutes. So I decided to have the chemical peel done.

My son took me to the office the day the procedure was to be done. He was still in medical school at that time, and he later told me that he was horrified that the peel was being done in nothing more than an examining room. There was no monitoring equipment, no crash cart, nothing.

One of the reasons that I decided to go ahead with the peel was that I didn't have to have general anesthetic. Dr. Hegre told me that he would just give me something "to take the edge off." But whatever it was he gave me, it knocked me out completely, I was not even semiconscious.

Dr. Hegre sent me home right after the chemical peel was done. I have absolutely no memory of the next four days. But my family tells me that I was delerious from the pain. Dr. Hegre had gave my husband pain killer injections -- demerol, percocet and valium -- to give me every four hours. But they didn't stop the pain. My family tells me that I was hysterical it hurt so much, that I said that my face felt like it was on fire. My daughter even put gloves on my hands and taped the gloves to the sheet so that I couldn't try to take the tape mask off my face.

Over the next 48 hours, my husband repeatedly called Dr. Hegre. His only real advice was to "just try to keep her calm."

On the third day, Dr. Hegre came to the house and removed the tape. My family tells me that they are convinced he knew then that something had gone wrong. Dr. Hegre had told me that the tape mask would easily come off. But here in this picture, Mr. Chairman, you see Dr. Hegre climbing all over my bed cutting the tape off. The pain was so terrific that I just wanted to die.

Finally, on the fourth day, I began to realize what was going on around me. The pain had lessened a little by then, but the itching was terrible. When I looked in the mirror, I was horrified. I looked like a monster, with hideous scabs all over my face. And I also realized for the first time that Dr. Hegre had put the acid on my eyelids, after I had told him not to.

When Dr. Hegre came to the house again on the sixth day, he put ointment on my face, which was supposed to encourage the scabs--or mask as he put it -- to slough off. But it didn't. I could tell then that he was really alarmed that it didn't seem to be working as he expected.

Then Dr. Hegre began to cut the scabs off my face. After that, the severe pain came back. But he still kept cutting the skin off, since it was not coming off naturally as expected.

At no time during this entire period had he ever prescribed any antibiotics for me. Even I knew that an open wound -- and particularly a burn -- is very susceptible to infection. And by that time, Dr. Hegre wasn't even prescribing pain killers for me either.

This went on with no change until a friend of my daughter's saw me, became really frightened for me, and immediately called his father -- a physician -- to come to our house immediately. When he saw me, he sent me to see a dermatologist right away.

I shudder to think what would have happened if that doctor hadn't come to see me.

The dermatologist told me that the acid had eaten away four layers of skin on my face. He immediately prescribed oral antibiotics and antibiotic ointment. I began to see the dermatologist regularly. But even under his excellent care, my face stayed blistered for over two months. And it was still raw for more than three months. Needlessly to say, the pain continued to be severe through all those weeks. My face was so tender that it was agony just to walk across the room with with any breeze at all.

His concern over the damage to my eyes prompted the dermatologist to send me to an opthalmologist. I was scared to death when he told me that the acid, in his words, "had burned three layers of my corneas." He went on to tell me that if one more layer had been burned, I would have been blind.

For weeks, I literally had holes on my eyelids and under my eyes. My eyelids were so damaged and swollen that they wouldn't close. For a while, the opthalmologist thought that I would have to have surgery to allow them to close, and to prevent further injury to my corneas. But I was lucky, and my eyes finally healed.

I will never see normally again. Contacts can't correct my blurred vision and I can't wear glasses anymore because of all the scar tissue on my nose. But I can still see, and for that I'm very grateful.

Today, I still see the dermatologist regularly because I get recurring cysts and inflammation. The only way to try to control them is to get steriod injections, but I worry about the long-term effects from those drugs. Nevettheless, I'm left with little choice.

When I look back on the last four years, I appreciate how far I've come. I remember that first Christmas. It was just three weeks after I had the chemical peel, and I remember vividly that my family and I thought it was the best Christmas we had ever had --because we all knew that I was lucky to be alive.

I remember, too, how I felt each time I had to put ointment or peroxide on my face. I felt like I was touching a monster. Weeks and even months afterward, I looked in the mirror and was horrified and replused by what I saw. I hated the way I looked and I wondered if it would change the way I felt about myself and the way my family felt about me.

But I'm the fortunate one. I'm fortunate because I'm here, because I can see and because I have a family that helped me through. I'm stronger because of this and so is my family. But not one more person should have to go through this.

Just one final note, Mr. Chairman. On top of everything else, Dr. Hegre tried to bill my insurance company for the chemical peel. I have here the insurance form that Dr. Hegre filed. It says that I had "impaired upper lid reflex" and "actinic keratoses of the face". I had neither, but it's my understanding that those conditions <u>are</u> covered by insurance, where cosmetic surgery or procedures are <u>not</u>. I think this form speaks for itself.

Mr. Chairman, I want to thank you again for asking me to be here today. I hope that my testimony will help you make sure that patients are protected from untrained doctors who do more than they should and can do safely. I think that doctors <u>and</u> patients are being tricked into believing that there is no risk from these cosmetic procedures. It's patients like myself -- and many less fortunate -- who pay the price. And the price is too high.

TESTIMONY OF THE AMERICAN ACADEMY OF DERMATOLOGY

AND

THE AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY

before the

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

of the

COMMITTEE ON SMALL BUSINESS

UNITED STATES HOUSE OF REPRESENTATIVES

November 2, 1989

Mr. Chairman and Members of the Subcommittee:

My name is Dr. Thomas Jansen. I am formerly Chairman of the Department of Dermatology at the University of Arkansas; Immediate Past President of the American Academy of Dermatology; and a practicing board certified dermatologist from Little Rock, Arkansas. Accompanying me today is Dr. Harold Brody, a board certified dermatologist in private practice in Atlanta, Georgia, and a leading authority on chemical face peels. Dr. Brody has been active in teaching dermatology at Emory University; is a member of the American Academy of Dermatology; and is a member of the board of directors of the American Society for Dermatologic Surgery.

The American Academy of Dermatology is a national medical specialty society which represents more than 8,000 practicing physicians of dermatology. The American Society for Dermatologic Surgery represents approximately 2,000 dermatologists who specialize in the diagnosis and surgical treatment of diseases of the skin.

We commend you and this subcommittee for your review of cosmetic surgery. As the popularity of safe, effective cosmetic surgery increases, it is important to insure that patients are not misled and that they are educated concerning the advantages and disadvantages of these procedures. Furthermore, it is paramount that physicians be appropriately trained to offer these services.

The Academy testified before this panel on April 4 of this year and discussed the specialized training received by all dermatologists and dermatologic surgeons. We will, therefore, limit our comments to the specific issue under discussion this morning: facial chemical peels. Dr. Brody and I will then be pleased to answer questions.

Chemical peeling (chemexfoliation) is a relatively common dermatologic procedure. It consists of the application of a chemical agent that destroys superficial layers of the skin, resulting in peeling of those layers.

The benefits of chemical peeling are many, increased feelings of self esteem and self worth paramount among them. The procedure's increasing popularity and acceptance indicates that patients often consider the benefits worth the risks, which are minimal if the procedure is properly performed by a well trained physician.

It is widely believed that the use of chemicals to improve the condition and appearance of the skin goes back to ancient times. Dermatologists have been pioneers in modern chemexfoliation since the turn of this century. Since that time, substantial progress has been made in understanding both the nature of the skin and variations of the treatment under discussion this morning.

Most people think of skin peeling as a way to rejuvenate the skin, and indeed this is one of its uses. However, it is also an effective treatment for removal of a number of skin abnormalities and it is increasingly believed that skin peels may prevent the development of skin cancer. Precancerous growths and probably early cancerous growths are destroyed in the peeling procedure.

Facial peels can be divided into three categories:

Superficial peels consist of the application of mild acids or acid like chemicals to treat problems such as pigmentary changes, fine wrinkling, or scarring. Often used is a low concentration of trichloracetic acid or one of a number of other mild acidic solutions.

Light peeling is generally safe, effective and inexpensive.

It produces excellent results and enjoys wide patient acceptance. There are usually no significant complications.

Medium depth peels are commonly used for photoaged skin, warts and wrinkles. They will usually produce improved results over superficial or light peels but do not expose the patient to the increased risk of complications associated with deeper phenol peels.

Deep facial peels, usually performed with the more toxic chemical phenol, are used for more severe abnormalities. They are the most extensive of the procedures and require thorough patient screening and evaluation and extensive training on the part of the physician performing the procedure.

Deep phenol full facial peels can cause more severe complications and side effects such as pigmentary and textural changes; scarring; infection; erythema (abnormal redness of the skin); atrophy; and cardiac or kidney problems.

Proper patient screening and selection is imperative. Physicians should be careful in recommending the procedure to individuals with skin types IV - VI (olive, brown or black skin). Darker skinned individuals experience a higher percentage of complications and often require a longer period of time for the skin to return to normal.

Other contraindications include: a history of herpes simplex; keloid formation; and history of cardiac disease. People on certain medications, or who have taken Accutane (a drug for severe scarring acne) or photosensitizing drugs, should not undergo the procedure until an appropriate amount of time has lapsed, if at all. Individuals with kidney problems should probably avoid phenol peels because of possible renal toxicity.

Only patients with a thorough understanding of the procedure, its risks and benefits, and its possible side effects and who have realistic expectations should be considered as facial peel candidates.

Chemical face peels, especially deep full face peels, should only be performed by physicians with extensive knowledge, training and experience in skin types, the care of normal skin, the diagnoses and care of diseases of the skin and adjacent tissue, and in cosmetic procedures.

Most chemical peels are performed by dermatologists, plastic and facial plastic surgeons and otolaryngologists who are thoroughly trained in the procedure and its possible complications and treatment, and who can provide extensive pre- and post-peel patient evaluation and follow up care. This is a medical treatment and not a procedure to be performed by lay people, such as aestheticians and cosmetologists, or by inadequately or poorly trained physicians.

You asked that we address in our testimony the issue of "Exo-dermology" and the marketing of chemical face peels.

In 1987, the Academy petitioned the Federal Trade Commission to investigate organizations known as the World Health Exodermology Center; the Medical Marketing Services, Inc.; and the Perma-Derm Academy. Our concerns were many; I will highlight a few.

Exodermology is a coined term with no meaning in the medical lexicon. Brochures from the World Health Exodermology Center have claimed that exodermology is a recognized AMA specialty. It is not. From what we have learned, Exodermology is a term used to describe a full phenol facial peel.

The Academy is extremely concerned that in addition to false claims of medical legitimacy, World Health Exodermology Center

promotional materials minimize the substantial risks associated with a delicate and potentially dangerous medical procedure that should be performed only by thoroughly trained physicians, after appropriate consultation with the patient.

Medical Marketing Services, which appears to be affiliated with the World Health Exodermology Center, aggressively markets "endodermology", yet another fictional name with no meaning in the medical lexicon. Its promotional materials, in addition to minimizing risks, claim individuals can learn a "safe" system of face peels in just one week. This is simply not possible and has the potential of putting many individuals at risk of serious disfiguring injury. Dermatology residents, for instance, spend three years in training to learn the structure and function of the skin, with a significant portion of this time dedicated to the learning of dermatologic surgery.

Chemical face peeling requires a knowledge of the full spectrum of chemical peeling agents. Exodermology provides one type of peel only, for all patients, without regard to the fact that deep peels may be required only on certain areas.

Patients may not be warned of all the potential complications of these peels, are lulled into a false sense of security, and are subjected to the multiple toxicities of the chemical, phenol, which can induce heart irregularities and complications such as those listed previously.

Finally, the Academy's complaint to the FTC addressed the Perma-Derm Academy which purports to license and certify "dermologists". Again, dermologist is a coined term and designed, in our opinion, to create the impression that its graduates have training and qualifications similar to those of board certified medical doctors. It is no coincidence that the words dermology and dermatology are similar.

In conclusion, there are several points regarding chemical face peels which should be considered by both patients and physicians:

- o Chemical face peels are a legitimate medical procedure with significant risks as well as benefits.
- o There is no one chemical or chemical mixture appropriate for every patient.
- o There are patients with certain conditions who are inappropriate candidates for the procedure.
- o Lay people or inadequately trained physicians should not perform chemical face peels.
- o Patients should be fully informed as to the risks of possible complications and have realistic expectations before undergoing a facial peel.

Mr. Chairman, we thank you for inviting us to testify this morning, and we will be pleased to expand on our comments and respond to any questions.

DR. MARK MONTGOMERY

STATEMENT BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

NOVEMBER 2, 1989

Mr. Chairman, Members of the Subcommittee, staff and interested parties, I welcome the opportunity to appear before this subcommittee and hope that my testimony will be helpful.

I am Dr. Mark Montgomery, a toxicologist currently employed as Director of the Toxicology Laboratory at the V.A. Hospital located in Tampa, Florida. I am also a full professor of toxicology at the University of South Florida's Colege of Public Health.

Since graduating from Johns Hopkins University with a Ph.D. in biochemical toxicology in May of 1972, I have taught toxicology on the faculty of several major U.S. universities. During that time I have taught virtually all aspects of pharmacology (the beneficial and adverse effects of drugs) and toxicology to medical students, dental students, nursing students, pharmacy students, graduate students (working on research degrees) and hospital staff.

Additionally, I serve on the Editorial Board of the Journal of Toxicology and Environmental Health.

Mr. Chairman, I also routinely provide expert opinions on toxicology for numerous state agencies, including the Florida Departments of Labor and Criminal Investigation. I assist by describing and exlaining the cause and effect relationships between chemical exposures and the allegedly resultant injuries. I have served as an expert witness for the Florida Department of Professional Regulations regarding medical malpractice resulting from doctors' misuse of chemicals on numerous occasions. My testimony in those cases is as a trained toxicologist with nearly two decades of experience, not as a government witness. It is in that same capacity that I will be testifying here today.

On October 24, you wrote to me about your concern that many unqualified doctors and lay people are performing medical procedures for which they have little or no training. It appears that greed and the quest for profits have replaced sound and proper training. As a South Floridian, I too share the Subcommittee's concern over the rampant growth of deceptive medical advertising and the blanket promises that countless medical procedures are safe and risk free.

Specifically, you have asked me to provide my expert opinion to the Subcommittee on the toxicity of phenol and trichloroacetic acid (TCA).

I believe that both chemicals used for face peels in the hands of untrained doctors is equal to the disaster waiting to happen when drunks hit our highways. The more times the individual operates, the nearer and more likely the disaster.

Phenol, also known as carbolic acid, is an extremely toxic, corrosive chemical that will dissolve protein and, hence, human skin. As a result of this toxicity, standard laboratory practice is to wear protective gloves and a face mask anytime this chemical, or solutions of this chemical, are being handled.

It is my opinion that application of phenolic solutions to the face places the recipient at a high degree of risk for development of mild to severe chemical burns. These burns may lead to a number of toxic results, including extreme pain at the site of application, irreversible scarring, and permanent skin discoloration. Additionally, the denuded areas of the underlying layers of skin that will develop immediately after application will be highly susceptible to infection due to removal of the barrier layers.

Since this chemical is being applied to the face, it shold be emphasized that the eyes are highly vulnerable to chemical burns, due to their lack of a protective barrier. Any small degree of splashing or inadvertent application to the surface of the eye would lead to immediate and severe pain with the possible final result of partial to complete blindness.

Regarding, trichloroacetic acid, virtually all of my previous comments on the dangers of phenol are applicable. TCA is a very strong, penetrating acid that is used routinely in my laboratory and others to precipitate (coagulate) proteins. It must be handled with extreme care and will cause severe pain and chemical burning upon dermal application.

From a toxicological point of view, it is very difficult to imagine an appropriate amount of phenol TCA -- even diluted-- being applied to the human face. The resulting burns could be devastating and the possibility of infection is tremendous. A mere drop of phenol acid in the eye could bli[illegible] a person for life.

Mr. Chairman, I am not a plastic surgeon or a dermatologist. I can perhaps imagine a very limited and specific situation where, in the hands of a highly trained specialist, utilizing proper antiseptic precautions, on a proper skin type, with comprehensive follow-up care, there may be a role for these materials. However, aside from this very limited possible application in the hands of a highly skilled specialist, I cannot imagine a role for these highly toxic chemicals in human dermatology. In the hands of other doctors -- or lay people -- the use of these materials is barbaric and can result in death.

Thank you, Mr. Chairman, for the opportunity to assist the Subcommittee. I would be pleased to try to answer your questions.

STATEMENT OF MICHAEL L. WALERSTEIN

BEFORE THE U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

NOVEMBER 2, 1989

Mr. Chairman and members of the Subcommittee, my name is Michael L. Walerstein. I am President and owner of Medical Marketing Services, Inc. ("MMS") a marketing consulting firm incorporated in the state of Florida. With me today is my attorney, David Barmak, a partner in the law firm of Sherman, Meehan & Curtin, P.C. located here in Washington, D.C.

I am here today at the direction of the Subcommittee. I understand that the Subcommittee has been conducting an investigation into the cosmetic surgery industry and, in this regard, wishes to ask me questions pertaining to MMS.

MMS was incorporated in 1985 and, since that time, has operated as a marketing consultant in the United States. Specifically, MMS helps interested physicians learn how to market the phenol based chemical exfoliation procedure to their patients. For simplicity's sake, I will refer to this as a chemical face peel procedure. Since the formation of MMS, my wife, Donna, and I have been the sole employees of the company. I am employed full-time as President and Donna has worked on a part-time basis. Our offices are located in suburbs of Fort

Lauderdale, Florida. We are a "small business" in the true sense of the term.

With regard to my company, I wish to make clear that I am not a physician, nor is my wife. MMS does not perform or teach the chemical face peel process. Instead our role as a consultant is to show physicians how they can best market the procedure through the use of media kits and other advertising methods. If the physician is not already familiar with this chemical face peel process we contract with an experienced physician to teach the method. The teaching physician is not a staff member or employee of MMS and makes his or her own arrangements with the physician desiring instruction.

I am aware that the Chairman of the Subcommittee has expressed reservations about the chemical face peel process in general. I am not here today to debate the relative merits of this procedure as compared to the numerous other surgical and nonsurgical cosmetic procedures available to the public. That debate should properly be reserved for the experts in the area of cosmetic and plastic surgery. However, I will note that many esteemed and reputable physicians, including both cosmetic and plastic surgeons, believe that the beneficial effects of chemical face peels are both long-lasting and relatively risk-free when properly performed.

For the Subcommittee's information, I have attached to my statement, a copy of an article concerning the chemical face peel

process which appeared in the Journal of the American Society of Plastic and Reconstructive Surgeons, Inc. in May, 1985.

Although I have not attended the Subcommittee's previous hearings on the cosmetic surgery industry, I have read several of the statements made by Subcommittee members and witnesses. From this I have the sense that the concern is not just whether the various procedures are effective but also who should be performing these elective cosmetic procedures.

I can address what I perceive to be two of the specific concerns as follows. First, with regard to the efficacy of the chemical face peel, I can only point to the medical articles I have read, such as the one I have attached to my statement, and to the hundreds of men and women I have spoken to and heard from who have had the procedure performed and who believe that it has made a dramatic improvement in their looks and their sense of self-esteem. My wife, in fact, had the procedure performed five years ago and believes that it has made a significant improvement in the way she looks and feels.

Based upon my experience I believe the procedure to be a safe and proven nonsurgical procedure that can markedly improve a person's appearance and self-confidence.

I, too, am concerned with who should be performing the chemical face peel procedure, but perhaps my concern is somewhat different from that held by others. It is my understanding that many states allow non-medical personnel to perform non-surgical cosmetic procedures -- such as the chemical face peel. I believe

Florida is just one of those states. This allows individuals, such as beauticians and other nonmedical individuals, to perform the procedure legally.

My company has not, does not, and would not, market its media package to non-physicians. We believe that the procedure should be performed by a trained and licensed physician. We also believe that the rigorous medical training that licensed physicians undergo qualifies them to safely and properly perform this procedure. As part of our screening procedure, we require that prospective clients send to us their curriculum vitae and a copy of their current medical license.

The real issue as I perceive it, is that there is simply a competitive battle raging between members of the medical community as to who is going to reap the economic benefits of this lucrative market. To some extent, companies such as ours have fueled the demand for the procedure by helping to publicize the availability of this relatively inexpensive, effective treatment.

Another point with regard to the marketing of this procedure is that my company cannot and does not pass judgment upon whether an individual physician is a "good" or a "bad" doctor. We must assume that because the physician is licenced and has undergone the rigors of medical training that he is qualified to perform the procedure. If the particular physician believes that he or she has the adequate training and background to perform this procedure properly and effectively then he or she may legally perform the procedure. There are many public and private

authorities at both the state and federal level, whose job it is to monitor and evaluate a physician's performance and competency. I do not view that as my role.

However, my company does advocate the chemical face peel procedure. This procedure offers the patient a choice and an alternative to traditional cosmetic surgery. We believe it to be safer and more effective than many of the other more expensive surgical procedures available to the public. This is a valid position held by many members of the medical community and the public.

Finally, if I may say so, I was pleased to read the comments of one member of this Subcommittee who said the following at this panel's May 31, 1989 hearing:

> Misleading advertising and medical malpractice are not synonymous. A bad ad does not directly produce a bad surgical procedure. An unqualified practitioner could employ perfectly legitimate advertising, or for that matter, not advertise at all, and still perform bad surgeries. Similarly, it is conceivable that a qualified surgeon could place a misleading ad. So, the question we should ask today is, 'Without advertising, would medical malpractice cease to exist?'

I would answer the question posed by Congressman Hancock with a resounding, "No!" Clearly, malpractice occurs in the medical profession, regardless of advertising -- misleading or otherwise. As Congressman Hancock went on to note, the Federal Trade Commission has concluded, after exhaustive study of the effect of advertising on the cost of medical services in the field of optometry, that the increased competition advertising has generated did not undermine the quality of health care and

consumers have enjoyed considerable cost savings because of advertising.

A problem does exist with respect to what should be done about false or misleading advertisements. I believe this area is one that requires rigorous enforcement to curb abuses. As the Subcommittee is well aware, the Federal Trade Commission is conducting an investigation with regard to medical advertising. In this regard, I have furnished the Federal Trade Commission with examples of the advertising currently being used by MMS.

We have cooperated with the Federal Trade Commission's investigation and believe that we will be able to satisfy fully the Federal Trade Commission's mandate to protect the public without impairing our ability to promote competition and to provide a service to the medical community.

* * * *

Before concluding my comments I would like to summarize briefly my previous contacts with the Subcommittee that gave rise to my appearance here today. I speak of these contacts merely to make clear for the record why I was reluctant to appear here today. I remain hopeful that my actions will be understood when viewed in light of past events.

In the spring of this year, I was contacted by Subcommittee staff and was asked to meet with them on an informal, voluntary basis. I was informed that the Subcommittee was conducting an

investigation of the cosmetic surgery industry and that the Subcommittee was interested in learning about me, my business, and the industry in general. I agreed to meet with the staff. This meeting, with two of the Subcommittee's investigators, took place in my attorney's office in Florida on April 14, 1989.

I was pleased to meet with the staff of the Subcommittee to assist them in their investigation of the cosmetic surgery industry. During the course of the meeting, however, I became increasing concerned with the tone and the manner in which I was being treated by the Subcommittee staff. The meeting rapidly deteriorated from what I thought would be a productive meeting into a quasi-interrogation. This was to be the first in a series of unpleasant exchanges my attorneys and I were to have with the Subcommittee staff.

On April 25, 1989, following my meeting with the Subcommittee staff, Chairman Wyden wrote to ask me to testify before the Subcommittee in May of 1989 and to answer certain questions and to produce certain documents prior to the hearing. I declined the Subcommittee's invitation because my wife and I are the sole employees of a small business and we could not afford the time to travel to Washington, D.C. In addition, because of the hostile manner in which I had been treated by the Subcommittee staff and because I understood the focus of the investigation to be cosmetic surgery procedures -- an area in which I have no expertise or knowledge -- it appeared that there

was very little that I could offer to the Subcommittee's investigation.

By letter dated May 9, 1989 my attorney in Florida declined the Subcommittee's invitation to testify. Shortly thereafter I was informed, through my Florida counsel, that the Subcommittee had decided to issue two subpoenas duces tecum, one to Medical Marketing Services and one to me, because I had declined the invitation to testify.

I understand that on several occasions comments have been made to the effect that I took action to avoid service of the Subcommittee's subpoenas. I have heard, although I do not know for certain, that initial attempts to serve me and MMS failed because the process server tried to serve me at an old home address from which I had moved some time earlier but continued to use, on occasion, as an office.

When the process server learned my correct home address I was, in fact, out of town. However, the corporation's registered agent, Larry France, was at all times, able to accept service for MMS. In point of fact, MMS' registered agent readily accepted service on behalf of the corporation. Thus, any contention that I or MMS ever attempted to avoid service is without basis.

My present attorney, Mr. Barmak, was contacted by my attorney in Florida shortly after we were informed that the Subcommittee was considering issuing a subpoena. Mr. Barmak, although not then retained by me, called the Subcommittee staff to learn more about the matter and was told at that time that the

subpoenas had already been issued and sent to Florida for service. After I was served with the subpoenas I retained Mr. Barmak to act as my counsel. Subsequent to the receipt of the first two subpoenas I received additional subpoenas from the Subcommittee directed to entities with which I am not affiliated.

The scope of the first two subpoenas (directed to MMS and to me) was extremely broad and contained twenty-seven (27) separate requests for documents, not including the numerous subsections contained within each request. As part of these requests I was directed to produce, from the years 1984 forward: my federal and state income tax returns; telephone records and telephone message slips; monthly statements from all of my savings accounts, I.R.A.'s, money market funds, certificates of deposit and any other bank accounts, and any cancelled checks relating to any of these accounts; and travel vouchers and expense account documentation. In addition to this personal financial information, the subpoenas also sought what I consider to be highly confidential and proprietary business information from MMS, including documents containing trade secrets.

On June 6, 1989 MMS and I responded to the Subcommittee's subpoenas in writing and made a partial production of documents. With regard to the documents containing confidential and proprietary business information, MMS requested assurances that documents and information provided by MMS would be maintained in confidence by the Subcommittee. MMS stated that it would

produce, upon receipt of these assurances, the documents requested.

Since no such assurances were received from the Subcommittee, my attorney contacted Janina Jaruzelski (Assistant Counsel for the House Clerk) to inform her that the additional documents were ready for production and to inquire as to whether the assurances that had been sought with regard to confidentiality would be forthcoming. My attorney was informed that the requested assurance would not be given.

Since that time I have unfortunately found myself at an impasse with the Subcommittee. My attorney has requested an opportunity to meet with the Chairman of the Subcommittee in an attempt to discuss the matter. Unfortunately, that request was denied.

The reasons for my concerns and the rationale for seeking such assurances have been underscored and confirmed by recent actions of the Subcommittee. I understand that a number of my physician clients have been contacted by the Subcommittee staff. I further understand that many have been asked to give testimony before the Subcommittee and to produce documents. These actions appear to me and to my clients to be a form of harassment by the Subcommittee. Whether intentional or unintentional on the part of the Subcommittee, the result to both me and my clients will be a reduction in our business and ability to attract new clients.

I continue to be desirous of complying with the Subcommittee's legitimate and reasonable requests for information

and documents relating to its investigation of the cosmetic surgery industry. It is difficult for me to understand, however, how my personal finances and records could be relevant to the Subcommittee's investigation. Furthermore, I cannot comprehend why the Subcommittee has denied me assurance of protection with regard to any confidential business information that I may provide.

PRSUAS

VOLUME 75 · NUMBER 5 · MAY 1985

PLASTIC AND RECONSTRUCTIVE SURGERY®

Journal of the
American Society of Plastic and Reconstructive Surgeons, Inc.
Official Organ of the American Association of Plastic Surgeons
Official Organ of the American Society for Aesthetic Plastic Surgery, Inc.
Official Organ of the American Society of Maxillofacial Surgeons

Published monthly by
THE WILLIAMS & WILKINS COMPANY, Baltimore, Maryland, U.S.A. 21202

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Long-Term Histologic Follow-Up of Phenol Face Peels

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George Mackee, a dermatologist, started using neat phenol solution in 1903 as a treatment for acne scarring.[1] Thirty to 60 seconds after application, he washed away the solution with 95% ethanol. This treatment was repeated at 2-month intervals, generally for four to six times. He expressed great satisfaction with the results and saw no untoward sequelae in patients followed for 10 to 30 years. Almost 50 years later, Winter, in Budapest, used 20% phenol in ether for the permanent removal of freckles.[2] In the thirties, lay operators were applying phenol to improve the appearance of the aging face. Full-thickness loss of skin and hypertrophic scars were among the frightening complications during this era. In the sixties, plastic surgeons recorded striking improvement of facial wrinkles after phenol peeling.[3–5] Since then, the technique has been perfected and has received strong endorsement by the medical establishment.[6] Most plastic surgeons now practice some form of phenol peeling.[7]

No one doubts the value of face peels for prematurely aged skin exhibiting wrinkles and hyperpigmentation. It is also appreciated that the benefits are long-lasting. However, the histologic changes that underlie the manifest surface smoothing are debated. Fournier, in Paris, in a statement that is a model of vagueness, avers that "the long-lasting results obtained seem to be due to formation of new structures in the basal layer of the epidermis and superficial layer of the dermis."[8]

What exactly are these changes? The student reviewing the literature on the microscopic alterations wrought by phenol will be struck by the rudimentary state of knowledge. Not only are the findings meager, they are also contradictory and confusing. In truth, we are not much more advanced than Mackee and Karp's 1952 description of a biopsy of the back taken 1 month after six monthly treatments of liquid phenol. They observed that the collagen bundles in the upper dermis were more compact and arranged parallel to the surface. Little more has come to light since then.[1]

In 1960, Ayres applied phenol to actinically damaged skin of the neck, and like Mackee, he found a subepidermal band of new collagen, 0.3 to 0.4 mm wide, with parallel fibers arranged horizontally.[9] Ayres stated that dermabrasion had the same effect.[10] In the same year, Brown and coworkers treated rabbit ears with cresol or phenol. They too described thickening of the dermis with fibers in compact layers parallel to the surface.[11] They obtained biopsies from the face of a single patient who had received a full face peel 15 years earlier, commenting that the main change was subepidermal laminated "fibrosis."

In 1962, Litton published four photos, site not specified, presumably from a single subject, describing the findings 48 hours, 3 weeks, and 3 months after a phenol peel.[4] At 3 months, there was marked widening of the "stratum papillare." Histologists would be puzzled by Litton's terminology, such as "sclerosing edema," to describe an increase in the number and thickness of collagen fibers.

Litton and Trinidad subsequently made the quixotic remark that face peeling is "pharmacologically unsound" although certainly beneficial.[7]

In 1970, Spira et al. applied phenol to the thighs of six paraplegics, mainly to evaluate the effects of different concentrations of phenol, the

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importance of adding croton oil, and the value of a waterproof dressing.[12] After 2 to 3 months, they noted dermal thickening with deposition of new collagen mostly without lamination.

In 1974, Baker and coworkers took biopsies of facial skin from 22 patients who had been peeled 6 months to 13 years earlier.[13] An attempt was made to study the histologic changes underlying the clinical improvement and to determine whether the structural alterations were permanent. They concluded that the histologic changes lasted for many years. The results in this publication are illustrated in four photomicrographs. Two of these are paradoxical. It was concluded that there was increased elastosis and that the changes produced by phenol peeling were almost identical to those of actinically damaged skin.

In 1977, Behin and colleagues applied phenol to minipig skin, following the changes for 16 weeks.[14] They observed a zone of new collagen after 2 weeks, without lamination, increasing in thickness up to 16 weeks. Elastic fibers were definitely less than in untreated skin. They referred to the new collagen as a "scar."

Stegman divided the neck of a 55-year-old man into 16 segments, 8 being sun-damaged and 8 normal, and compared the effects of phenol, trichloracetic acid, and dermabrasion, taking biopsies from each of the 16 areas at 3 days, 60 days, and 120 days.[15] Regrettably, the numerous photographs in this paper are so substandard and blurred that it is difficult to match the text with the figures.

The feature that impressed Stegman the most was the constant development of an "enlarged papillary dermis." He surmised that this is the key to the unwrinkled, fresh-appearing skin following a peel. Stegman, like Litton, was content to characterize this band as a widening of the papillary dermis; he too calls this a "dermal scar." The term "scar" has negative connotations that should not be associated with the clinical benefits of phenol peel.

In summary, the histologic record is incomplete and controversial. Guinea pig and rabbit skin is very different from human skin. Moreover, thigh skin is not the equivalent of actinically damaged skin. Most published photographs reveal poorly prepared specimens in which the histologic details are obscured and difficult to interpret. The available evidence leaves us with only a limited understanding of what phenol peeling does to facial skin.

The purpose of a peel is to create a new surface that is smooth and unblemished. The candidates are usually middle-aged women who have had excessive sun exposure. They seek chemosurgery mainly to correct wrinkling, although accessory benefits include the removal of lentigines, mottling, and actinic keratosis. These alterations comprise the hallmark of photoaged skin. One cannot appreciate the changes brought about by the peel without good understanding of the histologic portrait of actinically damaged skin as described in light- and electronmicroscopic studies.[16,17]

Design of the Current Study

Patients are loathe to have their faces biopsied. We used the strategy previously employed by Baker et al.[13] This enabled us to compare peeled and unpeeled skin in the same specimen. The plan entailed obtaining strips of skin during face lifting of patients who had been peeled years earlier. The strips were generally 4 to 5 cm long, extending widely on both sides of the junction between peeled and unpeeled skin. The line of demarcation was easily discernible. Of course, the unpeeled skin, being further back, was more protected from sunlight, but this only served to highlight the effect of the peel on the more damaged skin.

At various time intervals following the peel, a face lift was performed. The shortest interval was 1.5 years, the next was 4 years, and the longest was 20 years. More than half the specimens were more than 10 years after the peel. Thus this material far exceeds any previous follow-up study.

After the peel, the patients were urged to protect themselves from sun exposure. Whether or not they heeded this advice, the aging process ground on. The contrast between peeled and unpeeled skin was greatest when the specimen was secured within a few years after the peel. Nonetheless, there were striking differences 15 to 20 years later. All the subjects judged the peel to have been successful cosmetically.

We were able to obtain a specimen from a woman with severe hypertrophic scarring 1½ years after a peel was performed by a lay operator. This provided an opportunity to compare a clearly unacceptable scar with the changes produced by a proper phenol peel.

The excised skin was fixed in Formalin, sectioned semiserially, and stained as follows: hematoxylin and eosin, periodic acid–Schiff for subepidermal basement membrane, Orcein or Luna for elastin, Mowry for acid mucopolysaccharides, van Gieson for collagen, and Fontana for melanin. All specimens contained treated and nontreated skin that was contiguous. Because of the remarkable durability of the histologic effects, we have chosen to describe the results mainly on patients sampled 10 years and greater after the peel.

Results

Histology of Unpeeled Skin

The specimens obtained years after the peel all showed moderate to severe elastosis, a reliable sign of major sun damage. The elastic fibers were thickened, dense, tangled, and curled, often showing elastotic degeneration into amorphous masses (Fig. 1). There were numerous telangiectatic vessels and a patchy perivenular infiltrate of lymphocytes, histiocytes, and mast cells. We have termed this chronic inflammatory reaction "heliodermatitis" (unpublished). The collagen was much reduced in the elastotic zones. There was increased ground substance shown by Mowry staining. Just beneath the epidermis there was an eosinophilic band of collagen, without elastin, the so-called Grenz zone. The dermal-epidermal junction was flat. This is the well-known dermal portrait of actinically damaged skin.[16]

The epidermis was disorderly, sometimes thickened, with loss of polarity from the basal to granular layer. The epidermal cells were variable in size, shape, and staining properties. The cells were often small with pyknotic nuclei. In three specimens, microscopic actinic keratoses were seen with atypia and an underlying lymphocytic infiltrate (Fig. 2). An early lentigo maligna was present in one specimen.

The melanocytes were increased in number, hypertrophic, unevenly distributed, and often clustered. The amount of melanin granules in the keratinocytes was strikingly variable; some cells were seemingly engorged while nearby ones scarcely contained any pigment (Fig. 3). This uneven distribution of pigment accounts for the well-known mottling of sun-damaged skin of fair-complected persons.

The basement membrane stained unevenly with PAS, usually being thickened, but it was fuzzy and thinned in places.

Most of these patients exhibited freckle-like, deeply pigmented macules with well-defined borders, the familiar solar lentigo (ungraciously called senile lentigos). These were common in our material, consisting of branching epidermal downgrowths, the tips of which contained dense quantities of melanin, produced by clusters of hypertrophic melanocytes (Fig. 4).

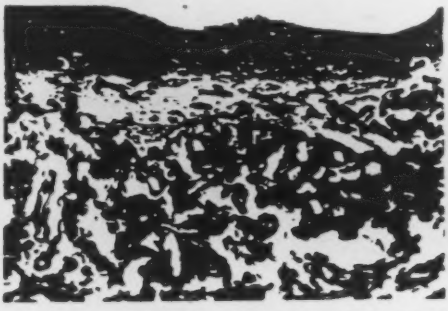

Fig. 1. Unpeeled specimen showing the major changes of advanced actinic damage. The epidermal cells are in disarray, showing variability in size and staining properties and loss of orderly differentiation. Beneath the flat epidermis there is a thin, clear band of collagen lacking elastic fibers, the so-called Grenz zone. The deep dermis is occupied by thickened, tangled, abnormal elastic fibers. This is the portrait of solar elastosis for which patients seek peels (Luna; ×406).

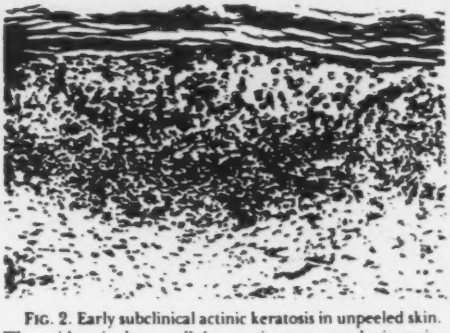

Fig. 2. Early subclinical actinic keratosis in unpeeled skin. The epidermis shows cellular atypia, great cytologic variability, parakeratosis, and a dense subepidermal lymphocytic infiltrate (H&E; ×460).

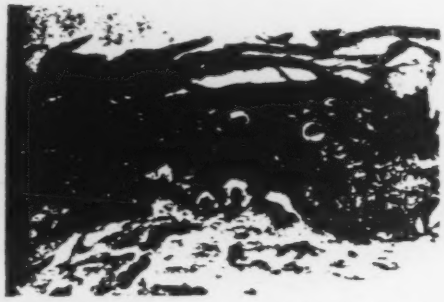

FIG. 3. Uneven distribution of melanin granules in the epidermis. Some cells are engorged with melanin, while others contain very little pigment. In the center are three adjacent, very large clear cells (hypertrophic melanocytes) (Fontana stain, ×650).

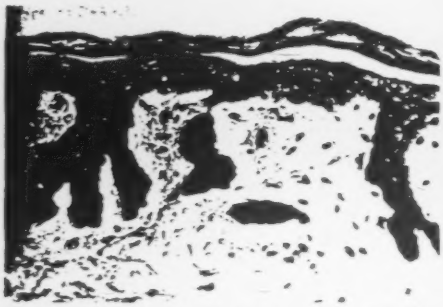

FIG. 4. Histopathology of the solar lentigo. Branching downgrowths of epidermis contain huge amounts of pigment secreted by numerous melanocytes clustered at the tips of the rete pegs (Fontana, ×406).

Histologic Changes in Peeled Skin

Dermis. Even under scanning power, the dermal changes were profound and conspicuously different from those in adjacent unpeeled skin. A new, wide band of dermis 2 to 3 mm in width had formed beneath the epidermis. This was sharply demarcated from the underlying elastotic mass representing the old unpeeled dermis (Fig. 5).

This newly formed band consisted of thin, compact, parallel collagen bundles arranged horizontally to the surface. These bundles were rather straight, in contrast to the usual waviness (Fig. 6, *above* and *center*). Fine elastic fibers, surprisingly numerous, coursed through this band, usually in random arrangement. Sometimes they were disposed in a parallel pattern conforming to the configuration of the collagen bundles. Even after 20 years, the fibers were still very fine and numerous (Fig. 7).

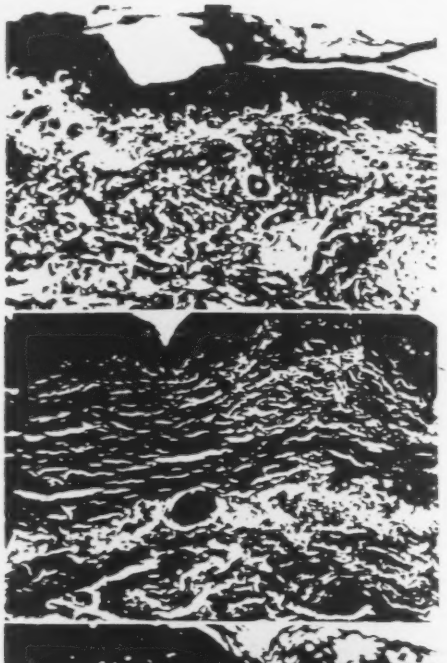

FIG. 5. (*Above*) Unpeeled specimen showing eosinophilic Grenz zone and marked dermal elastosis below. (*Center*) A 12-year postpeel view of a specimen from the same person showing a wide band of new parallel fine collagen bundles. (*Below*) Another patient 20 years after peeling. The reconstructed collagen band is about 3 mm wide. The old elastotic dermis is at the very bottom (van Gieson, ×406).

Within this new band, the ground substance demonstrated by Mowry staining was consider-

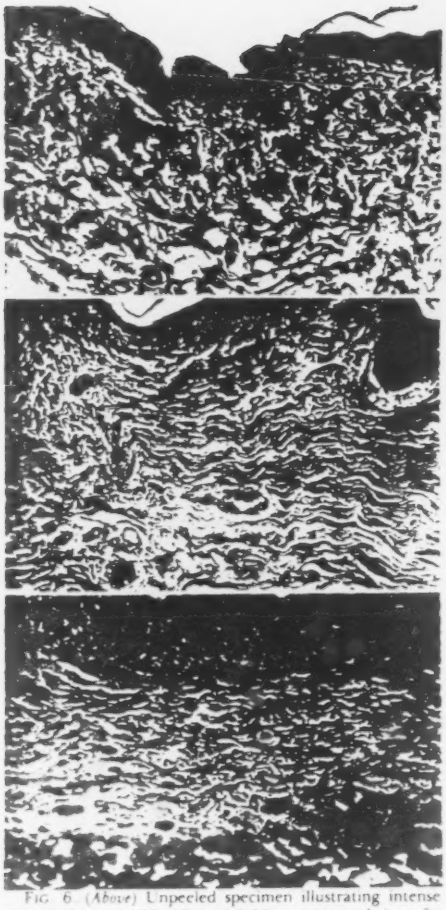

FIG. 6. (*Above*) Unpeeled specimen illustrating intense elastosis (Luna; ×406). (*Center*) A 14-year postpeel view of a specimen from the same person showing a wide band of horizontally arranged collagen bundles, among which course fine elastic fibers (Luna; ×406). (*Below*) Another patient 4 years after peeling showing the sharp demarcation between the new collagen band and the old elastotic dermis below (Luna; ×406).

ably less than in unpeeled skin. The small vessels within the reconstruction zone appeared to be normal. Telangiectatic vessels were confined to the deeper dermis, the portion not removed by the peel.

In contrast to the perivenular lymphocytic infiltrate in unpeeled skin, postpeel specimens

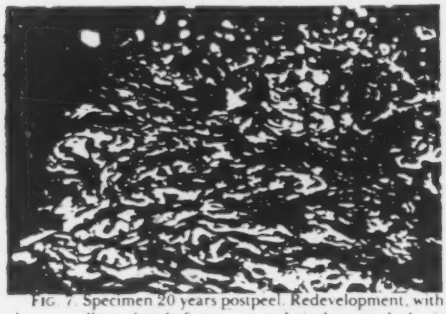

FIG. 7. Specimen 20 years postpeel. Redevelopment, with the new collagen band of numerous relatively normal, elastic fibers mainly parallel to the surface (Luna; ×382).

many years later rarely showed inflammatory foci around the newly formed vessels (Fig. 8).

Epidermis. The epidermis was altered toward a more normal pattern, showing a basal layer of columnar cells and a return of polarity. The cells were more orderly, without the cytologic irregularities of unpeeled skin. Lentigos were not seen. Also, there was no evidence of microscopic actinic keratoses.

The PAS basement membrane was more uniform in thickness and staining quality. The melanocytes were more regularly distributed, although some were enlarged with prominent cytoplasms (Fig. 9). The basilar cells of the epidermis contained many fine, evenly dispersed melanin granules (Fig. 10). The amount of melanin in adjacent cells was fairly uniform, although small.

Hypertrophic Scar. The dermis was thickened by a massive increase in dense collagen bundles arranged in parallel. Fibrocytes were increased. The spaces between bundles were narrowed. There were no sweat glands. Hair follicles were completely absent. The vessels were fewer, with thickened walls, often vertically oriented, here and there with extravasated red blood cells. Many fine elastic fibers were present, more or less horizontally arranged (Fig. 11).

DISCUSSION

Phenol peels produce dramatic changes that fully explain the clinical improvement. The most notable alterations occur in the dermis, where they are brilliantly highlighted by the colorful stains for collagen and elastin. The dominant event is the formation of a wide band of new dermis in which thin, straight, parallel bundles

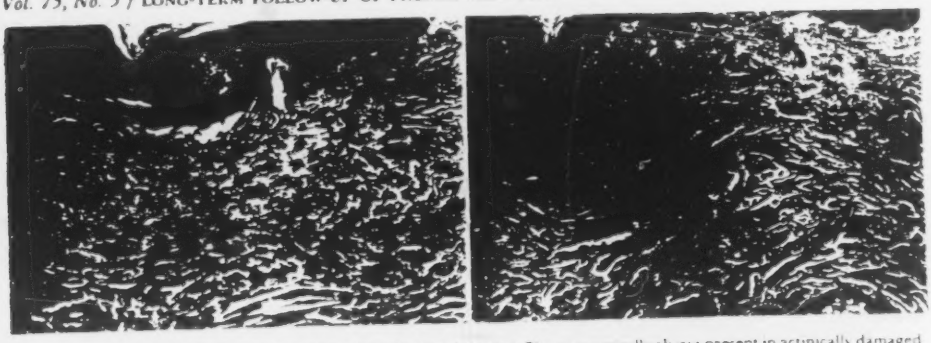

FIG. 8. (*Left*) Unpeeled specimen showing perivenular lymphocytic infiltrate practically always present in actinically damaged skin. (*Right*) Postpeel specimen from same individual 18 years later. There is no sign of inflammation. The population of dermal mesenchymal cells, including fibroblasts, is seemingly normal (Luna, ×153).

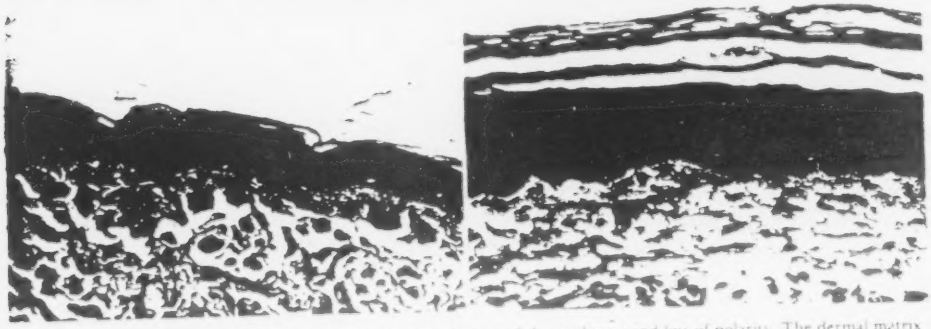

FIG. 9. (*Left*) Unpeeled specimen showing cytologic irregularities of the epidermis and loss of polarity. The dermal matrix shows large spaces (occupied by increased ground substance) and abnormal fibrous architecture (H&E, ×406). (*Right*) Peeled specimen from same subject 12 years later. There is a return of orderly differentiation accompanied by elimination of cellular variability. This is essentially a normal epidermis. The dermal matrix was of a normal appearance (H&E, ×406).

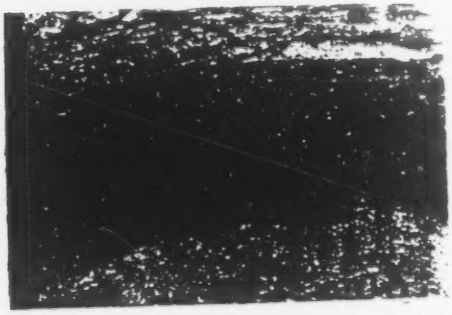

FIG. 10. Distribution of melanin granules 20 years after peeling. This is the same patient as in Fig. 3. The basal layer contains many fine pigment granules rather evenly dispersed (Fontana, ×650).

of compacted collagen are arranged horizontally to the surface.

The old dermis below is sharply demarcated from the new band, marked by a tangled, dense mass of abnormal elastic fibers. Both collagen and elastin are degraded in this elastotic dermis.

The new band contains normal small vessels with no evidence of telangiectasia. Telangiectatic vessels can be found in the old elastotic matrix below the level of the peel.

It is also quite clear that elastin fibers abundantly regenerate, forming a network of branched fine fibers often paralleling the distribution of the collagen bundles. These are of sufficient density and quality to at least partially serve the function of elastin by keeping the skin under tension and snapping it back after defor-

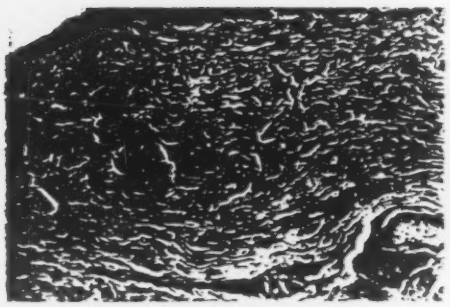

FIG. 11. Hypertrophic scar 1.5 years postpeel by a lay operator. The dermis is very thick, consisting of dense bundles of collagen with fine horizontal elastic fibers. Vessels are scanty. Sweat glands are completely obliterated. Hair follicles are not to be found, and mere remnants of sebaceous glands are detectable (Luna; ×150).

mation. However, the vertical subepidermal candelabra-like pattern of fibers in normal skin does not re-form.

The laying down of a new band of connective tissue adequately accounts for the effacement of wrinkles. From a review of the sections, one would expect the skin to be smoother, fuller, and tighter after the peel.

The dermal reconstruction persists a long time, certainly for at least two decades. The epidermal changes are also notable, although probably contributing less to the gross benefits of the phenol peel. The disarray and irregularities of sun-damaged epidermis are largely corrected. The cells are less irregular and show a more orderly pattern of differentiation.

Another noteworthy finding was the abundance of melanocytes in peeled skin. Plastic surgeons have repeatedly emphasized the permanent bleaching effect of a phenol peel. It is believed the hypopigmentation is due to destruction of melanocytes. This clearly is not the case. Melanocytes are present and even spottily increased. Moreover, they clearly synthesize melanin and pass it on to surrounding epidermal cells. We found that the latter contained many fine granules of melanin that were evenly distributed. Hence there is really hypopigmentation, not depigmentation.

Previous descriptions of the subepidermal band as "fibrosis" or a "scar" have to be interpreted carefully. While parallel collagen bundles are often found in scarred tissue, this similarity has to be viewed in the context of the clinical picture. Phenol-peeled skin is certainly not scarred in the clinical sense. It is soft and supple, not hard nor evidencing elevations or depressions. As is evident in the sections from the patient with hypertrophic scarring, such tissue contains no appendages and is very dense with decreased ground substance and increased fibrocytes. The clinical scar has fewer vessels that are often abnormally thickened with some extravasation of red blood cells. This picture scarcely resembles the subepidermal "fibrosis" of the phenol peel.

Finally, the complete destruction of the epidermis and its re-formation from the epithelial appendages account for the accessory benefits of the peel above and beyond the smoothing effect. Lentigines were eliminated. Moreover, mottling due to uneven distribution of melanin was also abolished.

We found small actinic keratoses in unpeeled skin, but none after peeling. Thus precancerous and probably other early cancerous growths are destroyed. We saw one early lentigo maligna melanoma in unpeeled skin. This is a superficial lesion that is doubtless removed by the phenol peel. Both dermabrasion and chemical peeling decrease the rate of appearance of new neoplasms.[18]

There is evidence that many actinic keratoses are subclinical, coming to light as "flares" during treatment with 5-fluorouracil. These inapparent lesions are universal in persons with a severe actinic damage, the very ones who seek "resurfacing" by phenol peels. It is likely that early basal cell and squamous cell cancers will likewise be destroyed by deep phenol peeling. It would seem, therefore, that the benefits of peeling are more than cosmetic.

SUMMARY

Deep phenol peels were done on 11 middle-aged white women with severe actinic damage. Subsequently, face lifts were carried out after periods of 1.5 to 20 years. This made it possible to obtain a full-thickness specimen extending several centimeters on either side of the border between peeled and unpeeled skin.

In contrast to the markedly abnormal elastotic appearance of unpeeled skin, a new band of connective tissue 2 to 3 mm in width was laid down in the subepidermal region. Fine elastic fibers formed a dense network in the band of regenerated collagen.

The disarray and cytologic abnormalities of

sun-damaged epidermis were also largely corrected. Melanocytes were not eliminated, but melanin synthesis was evidently impaired, accounting for the bleaching effects.

The effects of a phenol peel are very long lasting and adequately account for the effacement of wrinkles and obliteration of actinic keratoses, mottling, and freckling.

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To,
Hon.Congressman,
Mr. Ron Wyden,
Chairman,
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities,and Energy,
Washington,D.C.

Dear Mr. Wyden,

I received your letter dated 10/17/89 on 10/22/89.
I am given a very short notice to send material that your committee has requested,though will make an effort to assist you in your investigation.

1," Package" was furnished by Medical Marketing Services of Florida.
2, Training manual,Marketing manual was provided. Concepts and types of advertisements were also provided.
3, Marketing training was provided by marketing consultant. On sight training was given by a consultant who gave overall idea about how to talk to the people who made initial contact,how to present yourself,what are the expectations of the potential client,present them information in the manner that a lay person can understand,show them the photographs,and present them opportunity to watch video program provided by the company.
4, Medical training was provided by physician who has performed hundreds of procedures.Training program was eight days duration.I performed one procedure under supervision. I subsequently performed Seven procedures.
5, Services were marketed through newspaper,magazine,t.v. media.
6, To the best of my knowledge no complications have occured on my patients.

At no point any of the person was forced into undergoing cosmetic procedure. Several information booklets were mailed whosoever requested. Many came for further information which was offered in the form of presentation, which lasted thirty to fourty five minutes on average. Those who further wanted more information were scheduled for another separate appointment with me to explain the procedure,what it can do,what it can not do,what actually happens,how long the effect can last,who are the candidates, who are not the candidates,what are the risks,what are the complications,what are the bonus benifits. A thorough discussion was conducted in every contact that I made which lasted between an hour to hour and half.Histological microscopic changes that occur were explained with pictures

and diagrams with simple analogies to skin as a brick layer

on concrete foundation,changes occuring in the skin being compared to the paint film on exterior of the house wall undergoing changes through effects of elements in our enviornment.Simple analogies were given to conceptualise events that occur. All this was done at no cost to any person who showed enough interest to know about the procedure.Those who would not benefit from the procedure,who had still shown interest were given the same talk after they could spare time to listen to one.Every one was told how many procedures have I done before. Being a surgeon by profession
I can discuss complications without any hesitation,at a great length which I do all the time in my every day practice. There is a consensus in the community that physician does not spare enough time with patients or families which does not fit to my practice as I see Only Four to Six patients over Four hours of office time.

Procedure is done in the office only after thorough physical exam,extensive questioneer that patient has to fill in,lab work being performed extensively to screen patients. Patients are monitored with continuous electrocardiogram, and resuscetative equipment at hand and also with medications available. Following the procedure patients are closely observed,confined,cared for,fed,and visited every day including weekend which I do for my surgical practice as well.Patients are helped in every way to help endure time away from the family,which gives them better results,some loss of weight,which is a bonus for most,and also a chance to quit smoking for ever, and a piece of mind,and to catch up on the sleep and exhaustion from daily chores.

In my practice every patient is my friend and I am available to them every day and night of the week when I am in the town.

I invited the news media,and had a short segment on news cast,which T.V. station researched before airing it.

My patients who had the procedure done were very well educated, who had considered other options to change their self image. Procedure certainly helped to change their outlook toward themselves,as well as the others. Spouses were quite satisfied, twin sibling could certainly appreciate the difference ,Real Estate carrier zoomed sky high,with highest sales amount in the company.

Procedure is fairly simple to learn for any surgeon or for that matter any physician or even a lay person to learn. I see quite a few patients in my surgical practice with skin changes on face from sun exposure who could be candidates for the procedure but when they are reffered for a specific lesion,they are treated for that specific lesion by surgical excision,or by electrical destruction. This procedure is listed in procedure terminology manual of Blue Cross & Blue Shield. For someone who has extensive keratosis changes, chemical peel is the right procedure,and looking youthful afterwards is a big bonus. It also gets rid of premalignant changes which

otherwise would require surgical excision. I am quite cost conscious and always make every effort to save money for the patient as well as third party payer, as ultimately it is the consumer who foots the bill,including me as one of the utilising consumer.

As per recorded history about this procedure, it was initially performed by lay people,and physicians got interested afterwards.

I hope this sincere effort to answer most of your questions will help you in your investigation. If I have made any mistakes in addressing to committee members inappropriately please excuse me.

Sincerely,

10/31/85

MAJORITY MEMBERS
RON WYDEN, OREGON
CHAIRMAN

ELIOT L. ENGEL, NEW YORK
NORMAN SISISKY, VIRGINIA
JIM OLIN, VIRGINIA
MICHAEL R. McNULTY, NEW YORK

101st Congress
United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

MINORITY MEMBERS
WM. S. BROOMFIELD, MICHIGAN
LARRY COMBEST, TEXAS
MILTON D. HANCOCK, MISSOURI

STEVE JENNING
SUBCOMMITTEE STAFF DIRECTOR
205-225-7707

ANDREW POWELL
MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
205-225-6139

September 26, 1989

Mr. Michael Walerstein
Medical Marketing Services, Inc.
860 S.W. 89th Terrace
Suite 303
Plantation, Florida 33324

Dear Mr. Walerstein:

The Subcommittee on Regulation, Business Opportunities and Energy of the House Small Business Committee, pursuant to Rules X and XI of the U. S. House of Representatives, is conducting an investigation into the cosmetic surgery and procedures industry. To date, the subcommittee has held three public hearings to assess this industry, which is one of this country's fastest growing small businesses.

This investigation is an important part of this subcommittee's efforts to exercise the oversight responsibilities conferred upon it by the full committee pursuant to Rule XI of the Rules of the Committee on Small Business. Rule XI requires us to exercise oversight as to all of the regulation and business opportunities of small businesse, including the regulatory policies of Federal departments and agencies, and to continually evaluate the need for corrective legislation in these areas.

By the attached subpoena, you are directed to appear before the subcommittee on Thursday, November 2, 1989, at 10:00. The hearing will be held in Room 2359A of the Rayburn House Office Building in Washington, D.C.

This subpoena follows your actions over the last six months which were apparently designed to delay and thwart this subcommittee's efforts to gather even the most basic information regarding your national franchising of chemical face peels. As you well know, your voluntary cooperation was initially sought in April of this year.

The subcommittee reluctantly issued subpoenas to compel the production of documents, only after you repeatedly refused to respond to both my own personal requests and staff requests for information. The documents sought are directly pertinent to the subcommittee's ongoing investigation into the risks posed by various cosmetic surgery and procedures and the impact of various marketing and training trends on the medical marketplace.

You appeared to suggest -- through your Washington, D.C. attorney Mr. David Barmak, in his September 19, 1989, letter to the Chair -- that you had no intention of appearing before the subcommittee unless commanded to do so by subpoena. The Chair sincerely regrets having to proceed in this unfortunate manner. We fervently hope, however, that this subpoena and your anticipated appearance will at last afford you the opportunity to respond to complaints that have been brought to this subcommittee about your operation over the last nine months.

Consumers, doctors, lawyers and government regulators have raised concerns about the possible public health risks and the effects on competition of marketing enterprises such as yours. Since the subcommittee first began its investigation into these franchising operations, we have received letters and phone calls describing deaths and disfigurement at the hands of some of your alleged clients.

We are eager, therefore, to hear your response to these charges. The major focus of the subcommittee's inquiry is to attempt to identify factors fueling the trend of unqualified doctors performing procedures for which they are not fully trained, in facilities that too often lack even basic life support equipment. Your solicitation to doctors -- which emphasizes the profits to be made and your "safe proven system" -- appears to exemplify many of the elements of marketing trends that seriously trouble the subcommittee.

We look forward to your testimony on November 2, 1989. We will delay considering further subcommittee action on the previous subpoenas pending your testimony before the subcommittee.

Page Three

You are instructed further by this letter to provide the subcommittee with the basic information regarding your operation initially requested in the subcommittee's April 25, 1989, letter to you. That letter is attached to assist you in responding to the subcommittee.

Sincerely,

RON WYDEN
Chairman

WILLIAM BROOMFIELD
Ranking Minority Member

cc: Mr. David Barmak
Janina Jaruzelski

ORIGINAL

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES OF THE CONGRESS OF THE UNITED STATES OF AMERICA

To U.S. Marshal/or Frank Papineau/D.Ann Murphy

You are hereby commanded to summon Michael Walerstein

Medical Marketing Services, Inc., 860 S.W. 89th Terrace, Plantation, Florida 33324

to be and appear before the Subcommittee on Regulation, Business Opportunities & Energy Committee on Small Business,
Committee of the House of Representatives of the United States, of which the Hon. Ron Wyden is chairman,

in their chamber in the city of Washington, on Thursday, November 2, 1989,

in Room 2359A Rayburn, at the hour of 10:00 a.m.

then and there to testify touching matters of inquiry committed to said Committee; and he is not to depart without leave of said Committee.

Herein fail not, and make return of this summons.

Witness my hand and the seal of the House of Representatives of the United States, at the city of Washington, this 26th day of September, 1989

John D. Dingell
Chairman.

Attest:

Donnald K. Anderson
Clerk.

MEDICAL MARKETING SERVICES INC.

Dear Doctor:

An additional $100,000.00 to $400,000.00 can be added to your annual gross volume immediately, when you are trained in our exclusive methods of ENDODERMOLOGY.

The NON-SURGICAL FACE LIFT is now a perfected reality. Over the last twelve months doctors have been successfully trained in the process that turns back the clock of time 10 to 20 years and more in the appearances of a wide variety of satisfied patients.

The exclusive system is responding to the ever increasing demands of the 40 year old who wants to look like she did in her 20's, the seasoned professional who needs that younger look to compete, and the wrinkled senior citizen seeking a newer fresher look.

During our training, you will be taught to remove age spots, deep lines and wrinkles, some of which cannot be achieved by surgery or injections. Your patient will be left with NEW FRESH TIGHT SKIN that has the TRUE YOUTHFUL GLOW. Remember, this is new, fresh, glowing skin -- not the stretching of old, tired skin, and offers a viable alternative to the associated risks of some surgical procedures. MEDICAL MARKETING SERVICES, INC. will teach the qualified doctor in just one week, our SAFE proven system. Your staff will be taught the complete marketing, operational and back-up procedures.

Our marketing methods can eventually produce an additional gross income of $400,000.00 and more annually, year after year without appreciably increasing your current practice overhead.

If you feel you have the necessary qualifications, and desire more information about this expansion of your current practice, please complete the enclosed questionnaire and I will personally contact you promptly.

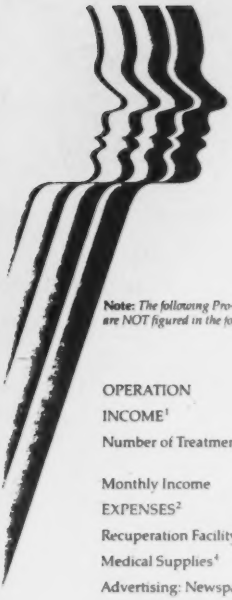
For immediate information, please call me during business hours at (305) 493-5573 or evenings and weekends at (305) 472-8218.

Sincerely,

Michael Walerstein
Director of Marketing

MEDICAL MARKETING SERVICES, INC.

MW:de



Pro-Forma

Endodermology™ System

Note: *The following Pro-Forma is based on you performing* ***Endodermology™*** *in your existing practice . . . Fixed current expenses . . . rent . . . phones . . . payroll . . . are NOT figured in the following . . .*

Cash Flow Projections For Endodermology™ Treatments

OPERATION	MONTH 1	MONTH 2	MONTH 3	MONTH 4	MONTH 5	MONTH 6
INCOME[1]	$10,500.00	$17,500.00	$24,500.00	$31,500.00	$35,000.00	$35,000.00
Number of Treatments	(3)	(5)	(7)	(9)	(10)	(10)
Monthly Income	$10,500.00	$17,500.00	$24,500.00	$31,500.00	$35,000.00	$35,000.00
EXPENSES[2]						
Recuperation Facility[3]	$1,440.00	$2,400.00	$3,360.00	$4,320.00	$4,800.00	$4,800.00
Medical Supplies[4]	450.00	750.00	1,050.00	1,330.00	1,500.00	1,500.00
Advertising: Newspaper	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00
Printing/Postage	500.00	500.00	500.00	500.00	500.00	500.00
Miscellaneous	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Expense Total	$5,890.00	$7,150.00	$8,410.00	$9,650.00	$10,300.00	$10,300.00
NET PROFITS	$4,610.00	$10,350.00	$16,090.00	$21,850.00	$24,700.00	$24,700.00

Total Net Profit for First Six Month Period: $102,360.00

First Year Proposed Net Profit: $250,560.00

[1]Gross Dollar Volume @ $3,500 per treatment
[2]Note: Rent, furnishings, utilities, salaries, and other fixed expenses have not been included.
[3]Based on $480 for eight day stay by each patient
[4]Based on $150 per patient

NOTE: This is an example of what can be achieved, and is not a guarantee.

© Medical Marketing Services, Inc. All Rights Reserved 1987

PASSPORT

To A Younger Looking You

©1987 MLW-Medical Marketing Services, Inc., All Rights Reserved.

You can look as young as you feel in just 8 days.

– non-surgically –

Our patients' results speak for themselves.

Enclosed photographs are actual patients' results, not retouched.

AFTER

BEFORE
AFTER

BEFORE
AFTER

AFTER
BEFORE

Questions & Answers

Q. IS THIS A NEW PROCESS?

A. No, Our procedure is a medically accepted treatment that was originally used by the rich and famous for over 50 years. It has been greatly improved and is now within the reach of all who want to now look younger.

Q. WILL THIS TREATMENT IMPROVE MY APPEARANCE?

A. Yes, by giving a new youthful appearance to your aging skin.

Q. WHO ARE THE BEST CANDIDATES FOR THIS PROCEDURE?

A. Generally fair to medium complexion patients take to the treatment the best, Very dark skinned people normally should not be treated. Your Doctor will make that decision.

Q. DO I HAVE TO BE IN GENERALLY GOOD HEALTH TO HAVE THIS PROCEDURE?

A. Yes, your doctor will determine if you are medically qualified.

Q. HOW DOES THIS TREATMENT DIFFER FROM CONVENTIONAL PLASTIC SURGERY?

A. This is a non-surgical office procedure, where a solution is applied to the entire face. There is no cutting or stretching of old skin with this procedure. The new skin regenerated is firm, with a youthful glow. Age spots and freckles are also removed.

Q. HOW LONG DOES THIS PROCEDURE LAST?

A. 10 to 15 years can be expected.

For further questions or a personal evaluation, please call the qualified physician's office listed on the back, for a free consultation.

MEDICAL MARKETING SERVICES INC.

Dear Doctor:

An additional $100,000.00 and more can be added to your annual gross volume immediately, when you are trained in our exclusive methods of ENDODERMOLOGY.

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Sincerely,

Michael Walerstein
Director of Marketing

MEDICAL MARKETING SERVICES, INC.

MW:de

Mail To:

Michael L. Walerstein

MEDICAL
MARKETING
SERVICES
INC.

860 S.W. 89th Terrace
Suite 303
Plantation, Florida
33324
(305) 493-5573

QUESTIONNAIRE

Name_____ Date _____

Practice Name _____

Type of Practice _____

Position_____

Address _____

City_____ State_____ Zip_____

Phone: (Business)_____ (Home)_____

Best Time to Contact _____

Length of Time in Practice_____

Annual Gross Volume of Practice _____ (Optional)

Staff Total in Practice: _____

Professional _____

Clerical _____

Note: This information is for our use only and will be held in confidence.

Comments _____

_____

_____

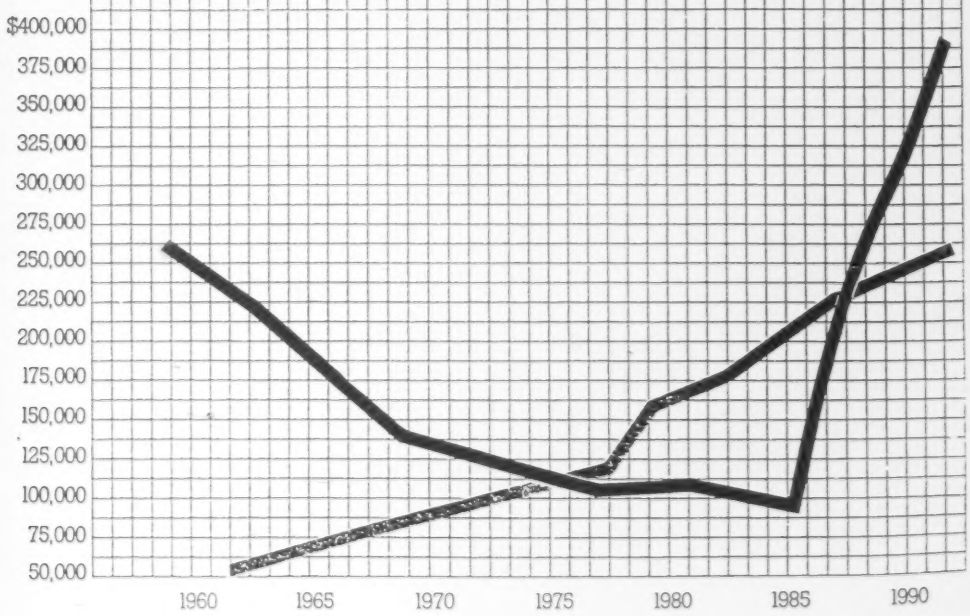
_____

Thank You

DEC 3 1987

A: ENDODERMOLOGY™

Q: WHAT WILL INCREASE YOUR GROSS EARNINGS WITHOUT INCREASING YOUR PRACTICE OVERHEAD?



IMAGINE LOOKING YOUNGER In just 8 days

BEFORE

AFTER

Yes. You CAN look younger in just 8 days. Imagine the benefits of NON-SURGICAL FACIAL RE-JUVENATION.

A proven and effective medical procedure is available now under the complete supervision of LICENSED PHYSICIANS.

A technique designed to remove wrinkles and blemishes from your face as well as 5, 10, or even 20 years from your appearance.

Call now for your
CONSULTATION
OR
SEE FOR YOURSELF!

Take this opportunity to meet actual NON-SURGICAL FACIAL REJUVENATION patients, share their experiences, and have all your questions about our medically supervised procedure answered at our

OPEN HOUSE
IN LOUISVILLE
Thursday, April 7 - 2 p.m.
Thursday, April 7 - 7 p.m.
ROOM I
KY. BLUEGRASS EXPO CENTER
9700 BLUEGRASS PKWY.,
LOUISVILLE, KY 40299
Saturday, April 9 - 2 p.m.
Saturday, April 9 - 7 p.m.
ROOM J
KY. BLUEGRASS EXPO CENTER
9700 BLUEGRASS PKWY.,
LOUISVILLE, KY 40299

IN FRANKFORT
Tuesday, April 12 7 p.m.
CAPITAL PLAZA HOTEL
405 WILKINSON BLVD.
FRANKFORT, KY. 40601

FOR MORE
INFORMATION CALL
1-800-248-1524
NO FEE... NO OBLIGATION

FACIAL REJUVENATION
CLINIC OF KY, PSC
275 NO. COURT ST. IRVINE, KY. 40336

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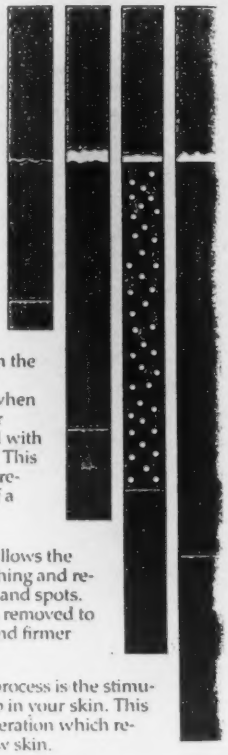
Endodermology

Clearly, there are advantages in *being* older, but not *looking* older. Everyone has a point in life when their skin begins to show signs of aging–a time when they wish they could turn back the clock on nature. Thanks to the Dermology Institute of America, Inc., the days of merely wishing are over. Now, men and women are learning of a medically sound procedure designed to reduce or eliminate lines, wrinkles, brown spots. Doctors and researchers have combined extensive research to pioneer a unique process of regenerative cosmetology called endodermology.™ Previously available only to the very rich and famous, endodermology™ is now possible for anyone in good health who wants to shed 10-20 years from their appearance.



The process of endodermology™ can best be explained by understanding the composition of your skin.

There are several layers which make up the outer skin, referred to as epidermis. The effects of nature, aging and exposure to the environment (sun, wind and pollution) manifest themselves as wrinkles, spots, and roughness in the epidermis.

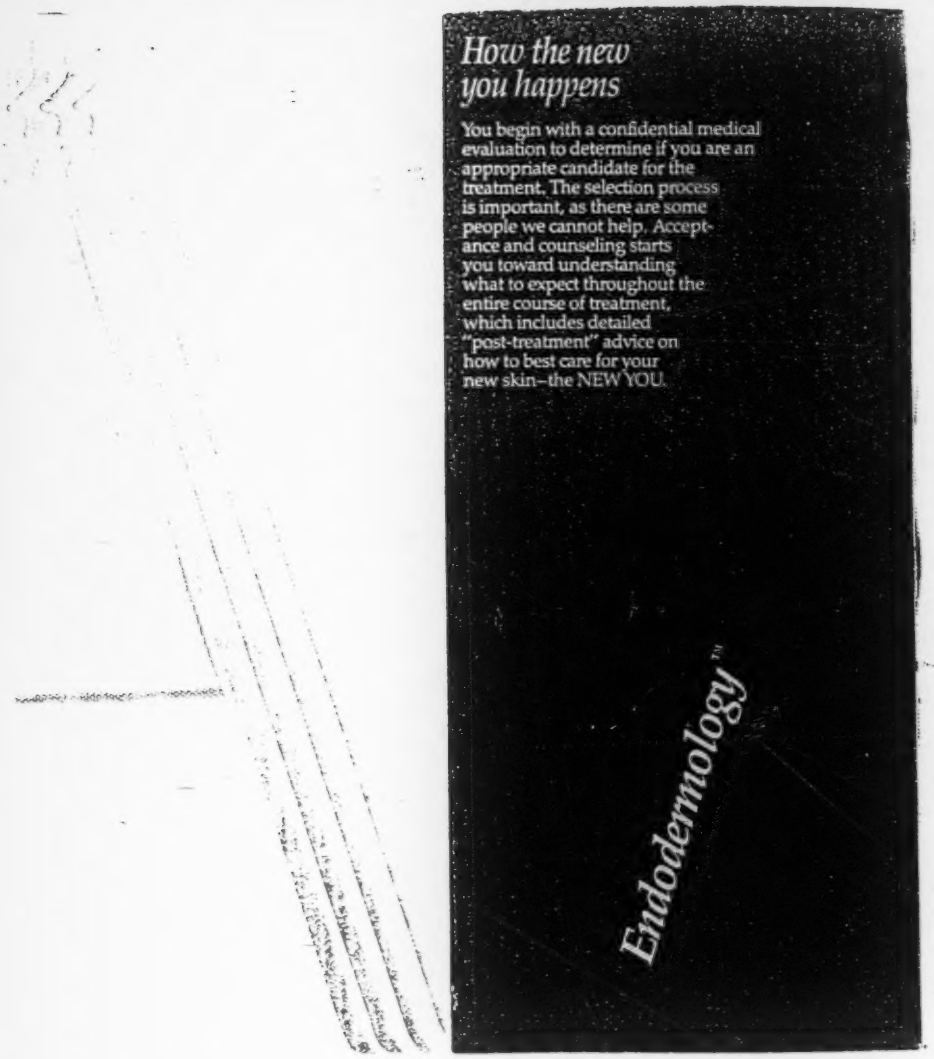
Endodermology™ works on the outer layers of skin. The regenerative process begins when a solution is applied to your face, neck, or hands, sealed with a surgical paper tape mask. This mask is soon removed and replaced by the application of a powdered mask.

With this mask in place, it allows the solution to work at diminishing and removing the wrinkles, folds and spots. Eight days later the mask is removed to reveal, a smoother, softer and firmer texture skin.

Another advantage to the process is the stimulation of dormant cells deep in your skin. This further enhances cell regeneration which results in radiant, healthy new skin.

The most remarkable aspect of endodermology™ is the enduring effects of the process. Soft, smooth, glowing new skin will be yours for years following the treatment, and as the aging process resumes, you will always continue to look ten to fifteen years younger by taking care of your health.

If your personal and professional life could be enhanced by the confidence that comes with looking your best, it's time to consider endodermology. Imagine a treatment that leaves you with a smooth, fresh, NEW skin that is soft to the touch and virtually free from wrinkles, blemishes and spots in JUST 8 days. Now is the best time to call and schedule a free consultation. A professional counselor is available for your no obligation conference, held in absolute confidence.


How the new you happens
You begin with a confidential medical evaluation to determine if you are an appropriate candidate for the treatment. The selection process is important, as there are some people we cannot help. Acceptance and counseling starts you toward understanding what to expect throughout the entire course of treatment, which includes detailed "post-treatment" advice on how to best care for your new skin–the NEW YOU.
Endodermology™

WORLD HEALTH EXODERMOLOGY CENTER

WORLD HEALTH EXODERMOLOGY NEWSLETTER

VOLUME I, ISSUE II SEPTEMBER 1985

This is the second issue of our monthly EXODERMOLOGY NEWSLETTER. The purpose of the letter is to serve as a medium for sharing experiences and providing information relating to the procedure.

As of this writing we have 25 trained physicians doing Exodermology in 29 areas. Our 1985 goal of 50 remains within reach and our goal of 300 will probably be attained by year end 1987.

We reiterate our plans to form a Society consisting of all World-Health-trained Exodermologists. Hopefully this will come to fruition by early 1986. We will be providing further information as we progress toward this goal.

EXODERMOLOGY:

It was our stated intention to have our second issue carry an article about patient selection. However, it has been brought to our attention that there may be more immediate interest in an article relating to after-treatment events.

The following is a step-by-step accounting of what takes place from the time of completing the treatment to the day of discharge. We suggest that you excerpt the article and prepare a hand-out to be given to all patients 5 to 6 hours after completion of the treatment. We suggest you do NOT distribute these BEFORE treatment. The following should be excerpted and "translated" into a "hand-out" to be given to each patient.

WHAT TO EXPECT AFTER THE EXODERMOLOGY TREATMENT

The following is a step-by-step accounting of what a patient will experience after the Exodermology treatment. It is a detailed explanation of what is to be expected on a day-to-day basis from the day of treatment to the day of discharge.

THE DAY OF TREATMENT: By the time you read this you will have received the treatment and will have

(Continued on page 2)

PROFILE

Dr. John Gaul

Dr. John Gaul, writer and editor of the newsletter and head of the department of Exodermology, is a transplanted Pennsylvanian who practiced in Florida for 31 years before becoming affiliated with World Health Exodermology Center. Dr. Gaul has been doing Exodermology since the early 1960's and believes he has done about 2,100 cases. This experience has made him ideally suited for his roles here as physician, teacher and consultant. Asked about his many hatted roles, Dr. Gaul kiddingly described himself as a "go-fer", since part of his work involves widespread travels to help Exodermology Training-program graduates with their first cases. Of course he is also very much a part of the intensive training program at the World Health Research Center. Exodermology graduates have found they can always count on good advice and cheerful alacrity on the part of Dr. Gaul, who makes himself readily available to answer questions and to help solve problems for those graduates who have completed their programs and are now out "in the field".

arrived at the after-care facility. During the 4 to 6 hours immediately after the application of the Exodermology solution and tape mask, your skin will be reacting to the solution. The (desired) "reaction" involves inflammation which means there will be swelling and subsequent discomfort. The degree and duration varies from mild discomfort to a very uncomfortable burning pain. Pain "threshold", that is an individual's perception of discomfort or pain is a determinant of how much medication is given. The majority of patients tolerate the discomfort without requiring pain-relieving medication beyond that given at the completion of treatment. But medication is available - - on "standby" - - ready to be given if indicated by any patient's need.

Ultimately, the inflammatory reaction (induced by the solution) reaches its limitation, after which the discomfort and pain ceases - - usually rather abruptly. This post-treatment discomfort usually has dissipated within 4 to 5 hours (average) which means that it may last 3 hours or less in one individual and 6 or more hours in another.

After the swelling of tissues has reached its maximum, the tape mask will have stretched and the mask will feel tense and splinted. Beneath the mask, the reacting skin is producing what is known medically as a protein plasma exudate. In simpler terms, the skin begins to "weep". The amount of exudate ("weep") varies considerably - - ranging from moderate to copious. In the latter, there may be so much "weep" that the individual must continuously blot with a towel. The (desired) effect of the weeping reaction is to debride (liquify) the outer skin layers. Before long the weeping exudate begins to penetrate the tape and the tense mask becomes wet and mushy. This is NOT a cause for alarm but rather the desired response. It is what is usual, normal and expected at this stage of the procedure. Of course these events take time and usually you will not have "arrived" at this point much before the second day.

THE SECOND DAY: (24 TO 48 hours after treatment). At this point a look in the mirror might be a little scary. A quick glance (if you can see through the slits in the tape) tells you that you could easily qualify for a role in "The Bride of Frankenstein" - - but this is as it should be. Usually, the tense firmness of the mask is greatest at about 24 hours after the completion of the treatment. But then, as more exudate ("weep") begins to form, the tape mask becomes wet and begins to soften and becomes stained in spots. At this point your eyelids and lips are swollen tense and this persists until the end of the second day and into the third day (second day following treatment). The treating solution has done its work and liquification of the outer layer of skin has been accomplished as intended. There is no need to be alarmed if the white (tape) mask is stained and discolored.

There isn't much to "do" for the first 48 hours after treatment. You may find yourself counting down the seconds - - wishing for a way to speed the passage of time. But about all you can really do - - is hurry up and wait.

THE THIRD DAY: (48 to 71 hours) Approximately 48 hours after the time of the treatment (plus or minus a few hours), the tape mask will be carefully removed, after which a powder is gently applied to the still-weeping skin. The initial powder application is done by the doctor and then continued by the patient until a firm powder "mask" has completely replaced the original (tape) mask. Usually, at this point, the heavy "weeping" has subsided somewhat. The powder mask serves a three-fold purpose: It is antiseptic (prevents infection), crust-forming (takes the place of a scab) and it serves as a rigid splint to maintain the face in a fixed position during healing. During this period, as long as the powder mask is in place, one should exert every possible effort to keep from using facial muscles by talking, chewing, etc.

THE FOURTH DAY: (72 hours until 96 hours after treatment): The powder mask stiffens and crusts are beginning to form at the facial intersections (the "corners" of the mouth and eyes, at the hair lines, around the nostrils, etc.). The most common problem at this point is itching. Not all patients itch, however. Once again, the amount and intensity of itching varies from

(Continued on page 4)

WORLD HEALTH EXODERMOLOGY NEWSLETTER

John Gaul, D.O.
editor

Raena Gordon
art director

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Left to right:(top) 1. Patient before treatment. 2. Following initial application of liquid, and paper mask. Patient will remain in this state for the first 48 hours.(Bottom) 3. Powder mask is applied 3rd to 7th day. 4. Final result.

patient to patient. Itching occurs as a normal part of the healing process and, if bothersome, can usually be well controlled with the help of antihistamines - - which are provided as needed. Another common problem at this point is the beginning of development of crusts on the eyelids. At least one in three patients has a problem with crusts. This is a self-limiting but uncomfortable part of the normal healing process.

THE FIFTH DAY: Healing continues. If there is itching, this is the time it is most likely to occur. The mask is heavier and firmer at this point. Eye "crusts" may also be heavier and more bothersome at this stage. Powder applications should be continued. Otherwise, there is little to do but HURRY and WAIT.

THE SIXTH DAY: Ditto

THE SEVENTH DAY: Ditto

THE EIGHTH DAY: (The fifth day of "wearing" the powder mask) Sometime during the morning the doctor will apply a lubricant to the powder mask. This penetrates the powder mask, lubricates the skin and causes the mask to fall away. The mask does not come off in one piece. It is a bit-by-bit process. In the AVERAGE patient, most of the mask has come off or at least become loosened by the end of the day. But that is not ALWAYS the case. Occasionally there are "bits and pieces" for an extra day or more. In no event, should you "pick" at the mask. Very gentle rubbing of the lubricant, using only the pad of the fingertip is sufficient. DO NOT use your fingernails (or anything else) to attempt to speed up the process of shedding the mask. If you do, expect a secondary crusting which has to go through all the same stages of healing. Rather than speeding the process, you will be risking the possibility of infection along with guaranteeing that the healing process will take longer. The lubricant will do its work very effectively without any need for "picking" assistance and the risk of complications.

THE NINTH DAY: (The day of discharge): By the morning of the ninth day, in the great majority of patients, the powder mask is completely gone. The underlying skin appears somewhat "splotchy" much like an uneven sunburn. Some areas of the "new" skin may be darker or lighter than other areas. This is normal and expected. Not everyone heals exactly like everyone else. There is no point in comparing yourself to someone else who is also in their ninth day - - but may have a somewhat different appearance. In some, the "splotchiness" is more evident than in others. In the majority of patients, the skin will have become confluently pink and homogenous in color by the end of the fourth week following discharge, although some unevenness of color may persist for 6 to 8 weeks or longer. Rest assured, that will resolve in time.

DISCHARGE DAY: If you're like most others, you're ready to jump out of your (new) skin to get going! The encumbrances of the uncomfortable masks and dead tissue are behind you. You've got a whole new outlook (and look). Nonetheless, before discharge, the doctor wants to survey the "new" face to be assured that everything is as it should be. Little more than a glance is needed but that quick look is absolutely necessary. Usually, the doctor will put in an early appearance as he is fully aware of how anxious you are to be on your way.

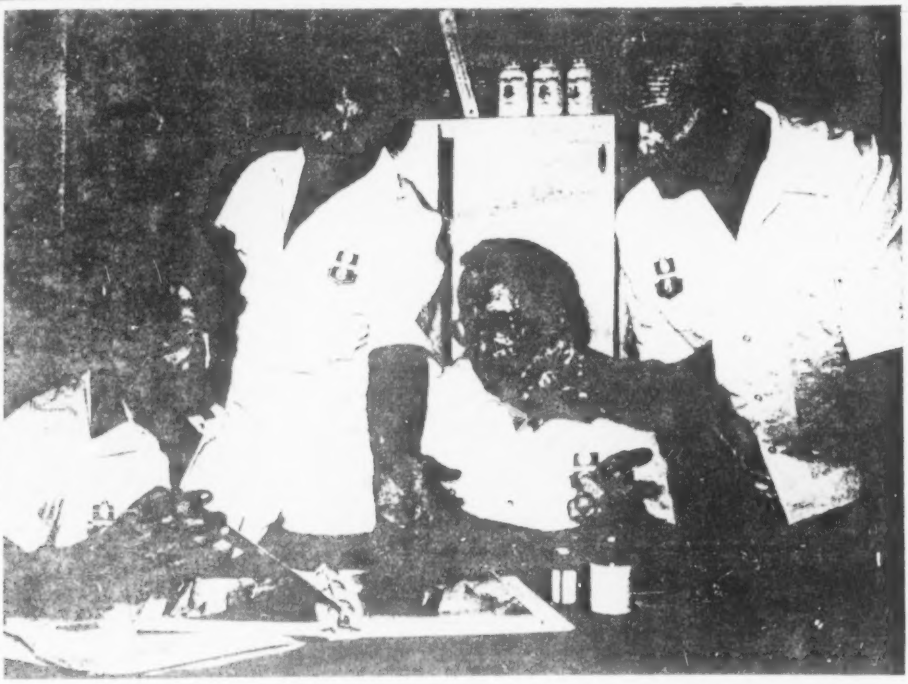
FOLLOW-UP CARE: The doctor wants to re-examine the result of his handiwork approximately 3 to 4 days after discharge. Call the office to arrange for an appointment time. Remember to wear a wide-brimmed hat and to cover your skin with a high-potency sun blocking agent for ANY outdoor excursions - - including your trip to the office.

POST-TREATMENT COSMETIC CARE: Skin changes that result from the Exodermology treatment do not suddenly cease, but continue for weeks to months after discharge. The "new" skin must be treated with tender loving care ("T.L.C.") to assure the maximum possible end-result. The following are suggested for cosmetic care for at least 2 to 3 months after discharge:

1. *PHISODERM* (antiseptic) soap for washing the face morning and night - - for one week, after which, switch to *NEUTROGENA*.
2. *CLINIQUE* Continuous Coverage (ask for it by name.)
3. *CLINIQUE* Moisturizer.
4. *CLINIQUE* Blusher.
5. *YOUNG AGAIN* Placenta Cream (One jar provided at the time of discharge) $25.00 per jar thereafter.

DAILY ROUTINE:

1. Wash your face with *PHISODERM*.
2. Apply *CLINIQUE* Moisturizer.
3. Cover with *CLINIQUE* Continuous Coverage.
4. Apply *CLINIQUE* Blusher.



Exodermologists Drs. Charles Curtis and Gus Prosch consult with Drs. Amnon Goldstein and Charles Hall, Medical Director and Staff Physician(respectively) of the Anguilla Health Spa, in Anguilla, British West Indies. (The Anguilla Health Spa is a Division of World Health Resorts, Ltd.) Left to right: Drs. Goldstein, Curtis, Prosch and Hall.

5. Wash off daytime makeup with *PHISODERM* prior to bedtime.
6. Apply *YOUNG AGAIN* Placenta Cream just as you would any night cream.

DO'S AND DO NOTS:

Some patients experience a flushing of the "new" skin from time to time during the first few days or weeks after discharge. This is exacerbated by stimulants such as coffee, tea and alcohol. The latter are best avoided. If the flushing is bothersome, apply plain yogurt to the face. The yogurt will be soothing and will also help to promote a more homogenous skin color.

DO NOT have your hair bleached or dyed for at least 4 weeks after treatment.

DO NOT use a HOT air dryer for at least a month. You may use a dryer but NOT HOT air.

DO NOT use any soap or cosmetic with a "built-in" fragrance. These fragrances are chemical in nature and can be irritating.

EXPECTATIONS: (Not complications).

1. It is not uncommon to have some secondary "flakiness" or peeling for a few weeks after treatment. This is merely evidence of an ongoing healing process

(Continued on page 6)

and should not be viewed as a cause for alarm.

(2.) "Splotchiness", i.e. unevenness of skin color may persist for weeks or even longer after treatment. This is NOT a cause for alarm. The homogenous color will eventually return.

3. As a consequence of the Exodermology treatment there is an ongoing rearchitecturing of the skin which persists for weeks or longer after discharge. It is not unusual to develop some whiteheads (pimples). This is a consequence of the very aggressive nature of the treatment. Sebaceous (oil-secreting) glands become more active during the healing process. Minor breakouts of pimples requires no special treatment as these are self-limiting. Doing NOTHING is preferable to doing something as almost anything you do will probable be the WRONG thing to do. The most important thing you must do is leave them alone.

LAST BUT NOT LEAST: If you have any questions or problems that arise - - and the answers are not to be found here, we are only as far away as your telephone. We are most happy to prevent problems by encouraging your communication. When in doubt about anything relating to Exodermology – communicate. You can call us anytime between the hours of 9:00 AM and 5:00 PM(Eastern Standard Time) Monday through Friday on our toll-free line: 1-800-LIFEPAC.

We hope that all of you will use our newsletter as a sounding board by posting questions or citing problems that may be of interest to all. We will appreciate any feed-back and we realize that there are always more questions to be answered.

WHAT CAUSES WRINKLING AND PREMATURE AGING (OF THE SKIN)?

Our second article for this issue expands on a question posed in our first issue.

In our first issue of the Exodermology Newsletter, we made references as to the causes of wrinkling and premature aging of the skin. In this article we delve further into those causes in the hope that those who have undergone Exodermology may institute some measures of prevention against future skin damages from preventable causes.

One of the most widely held theories relating to the causes of aging concerns highly reactive (chemical) molecules known as "free radicals". A "free radical" is a molecule with an unpaired "free" electron in its outer orbit. An unpaired electron whirling about an atom of oxygen, for example, causes that molecule to become superactivated – in other words, chemically eager to become paired or "mated" to some available molecular "partner". Almost anything unattached will fill the need. Being (chemically) indiscreet, it is not surprising that undesirable ("radical") molecular pairings occur when the "free" electron hooks up with nucleic acids such as those in RNA or DNA, the genetic blueprint materials that spell out or dictate the replication of cells that are used in repair and maintenance of body tissues and organs. The (undesirable) "free radical" molecular pairing may involve any protein, heavy metals,or almost anything that becomes available. The scientific term for these "free-radical" pairings is the process of cross-linking.

An example of what happens in an (oxidative) reaction involving "cross-linking" is what takes place when a liquid plastic is poured from a bottle and, with exposure to the air, oxygen "sets up" or hardens within a matter of minutes. The "cross-linking" that occurs is, in fact, the basis for the entire plastics industry.

It is difficult to imagine how much our lives would be changed without plastics. But the phenomena of "cross-linking" also has a bad side because "cross-linking" causes some things to become too stiff and too brittle - - including human beings. Many of the time-related changes that occur in aging, events that set the stage for disease, are actually a consequence of relentless, life-long and ongoing "cross-linking". It has only been within the past several decades that scientists have begun to recognize the vast influence of free radical activity and the ultimate consequences of "free-radical" activities on health.

Some cross-linking is "natural" and beneficial in that it gives rigidity and structural strength where that effect is desirable. A mushy-soft, super-flexible newborn baby that can put its toes in its mouth toughens into a muscular teen-ager, and to that extent the process is working in our favor. It would be wonderful if the process could be stopped at that point somewhere close to the ideal of physical maturity close to some point of structural perfection at which point we would not be too soft and mushy like a newborn baby but also not as stiff and inflexible as we become as we age and can no longer bend over to tie our own shoestrings.

Cross-linking events take place throughout our lifetime and we see the results of cross-linking all about

us in everyday life. It is why the meat of old animals is tougher, why old Jello shrinks away from its bowl and becomes rubbery hard. It is why old rubber bands become less elastic and eventually brittle, just as does an old windshield wiper or the rubber hoses in a car. Likewise, it is what happens to humans as they age. The older we get the less elastic we become. In some individuals the cross-linking events occur sooner than in others. The skin loses its elasticity. The aging eye is unable to accommodate as readily to distance. Arteries stiffen and harden. What was an elastic and flexible artery eventually becomes more like a plastic pipe, stiff and brittle as an old rubber hose in an automobile. The hardened artery is less elastic, it has less "give" so that the heart has to pump harder to circulate the flow of blood through the vascular system. There is an increase in tension within the artery (hypertension). Blood pressure rises sometimes to the point that a blood vessel ruptures. The inelastic artery splits and tears. Blood leaks from the tear. If the tear occurs within the brain, the victim has had a stroke.

Free radical damages and cross-linking affect the entire human system. Any and all cells and tissues may be effected in one way or another. The heart, the lungs, the kidneys, the vascular system and the skin – all organs – all systems. The immune system, for example, the function of which is to protect us from infections and cancer, becomes less efficient. Protective immune barriers are lowered and we become more susceptible to diseases of all kinds.

There are numerous sources of agents that lead to the formation of free radicals including the aldehydes from alcohol, radiation (sunlight, X-rays), heavy metals from tobacco smoke and other sources that pollute the air and water (lead, cadmium), certain chemicals added to foods (such as sodium nitrite, a meat preservative), chlorine, ozone, and even natural substances found in foods.

There are human "in-house" enzyme systems that partially help to control free-radical activity but the body's systems are inadequate and become increasingly less efficient with aging. Ultimately, ALL protective systems are affected, the body is overwhelmed and the final stiffness (rigor mortis) attests to the inadequacy.

When a patient presents with thick, wrinkled and aged skin, what you are observing is a consequence of cross-linking as it affects the skin. What is "erased" by Exodermology is the cross-linked epidermis. The "new" skin that results from the treatment looks like it does because it hasn't been damaged by the cross-linking events . . .at least not yet.

WHAT TO DO: Excerpt from this article and prepare a handout for your patients who would like to delay or prevent the reoccurrence of further wrinkling to whatever extent that is possible. Explain the benefits of prevention - - and the benefits of using antioxidants to prevent "free-radical" damages.

–NEXT ISSUE–

Our next issue will deal with the subject matter we originally intended for this issue relating to PATIENT SELECTION, which we deferred in favor of our feature article on WHAT TO EXPECT - - AFTER TREATMENT (by popular demand).

Also next month we will profile a nutritionist, ex-TV personality, and former Exodermology patient who will explain how your patients can take care of their skin internally.

LETTERS

Dear Dr. Bennett,

After reading the advertisement about the World Health Research Center, Inc., I went to see Dr. Bennett for a consultation. After talking to him, I made an appointment to have my face done. I not only look younger, I feel younger.

Friends and relatives say to me, "What have you done to yourself, you look great!" I smile and say that Dr. Bennett gave me a new face.

Thanks to the World Health Research Center, Inc. and Dr. Bennett. I would recommend that any women who needs it to have it done. It's worth every penny.

R.S.
Pompano Beach, Fla.

Dear Dr. Bennett,

Am delighted to say how pleased I am with myself. It's so nice to hear friends say "How well you're looking." When you're my age and see people quite a bit younger with aging skin, it makes you feel "So Good"

The staff at the office of World Health Exodermology Center are most considerate and helpful with us.

Dr. Bennett, you're really "Special" in every way!

Sincerely,
Mrs. M. T.

MIRROR MIRROR ON THE WALL

BEFORE TREATMENT

AFTER TREATMENT

20 YEARS ARE ABOUT TO FALL

EXODERMOLOGY is a non-surgical AMA recognized medical specialty that lets you get rid of wrinkles and blemishes in only 8 days... You can have a smooth youthful complexion that will wipe away the years from your face. Compared to a surgical face-lift, EXODERMOLOGY is quicker, less expensive, leaves no scars - and the results look better.

Your name and/or company here

Dear Dr. Bennett:

I want to thank you for the wonderful treatment you did on my face in removing all my wrinkles. My friends just can't believe the great change in my looks.

It is imposible for me to express in words the wonderful feeling it has given me psychologically.

Being 75 years of age it is a wonderful and happy feeling for me to look at least 10 years younger, which in turn makes me feel young.

My husband feels the same way. He now says I look like a teenager.

Sincerely,
(Mrs.) H.P.

Dear Dr. Bennett:

The last few days have brought great joy into my life as a result of the Exodermology treatment you gave me on August 27th.

During the treatment I was quite comfortable and was so grateful for your expertise, your concern, and the support of your assistant.

While at XANADU, the entire staff was available to meet every human need and the atmosphere there was peaceful and the environment conducive to complete relaxation.

Of course, I expected to have a NEW FACE when the final powder mask was removed . . . however, when I first saw the glowing vibrant flawless face . . . I had to be sure I was not on "FANTASY ISLAND" . . .that this was REALITY!

The reflection in the mirror resembled a photograph taken 30 years ago which was used for a nationally acclaimed public relations and fashion career.

Not only did you roll back many years, decades in fact, but X-ray scars caused by treatment for childhood acne are no longer visible to the naked eye.

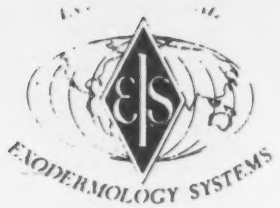
I am still in the healing stage at this writing, but I could not wait to tell you have thrilled I am!!!

My deepest gratitude goes to you and your entire staff, especially to Pat Casserly, your charming and patient Consultant. She gave me much reassurance and answered multitudinous questions.

With deepest appreciation and wishing you continuous joyous success,

Enthusiastically yours,
(Mrs.) A.F.S.

We are still seeking letters from patients and physicians. We would appreciate any contributions which you feel would be of general interest.



DEAR DOCTOR,

Did you ever want to be a Miracle Worker?

You can work miracles with Exodermology. After more than 7,000 treatments and 23 years of research, Exodermology is the latest, most advanced form of chemexfoliation, achieving more remarkable results than the procedures now commonly used. The photos tell the story. And here's what else EXODERMOLOGY has to offer YOU:

• *UPBEAT HEALTH CARE*: You make people look younger and better - and they love you for it!

• *ELECTIVE HEALTH CARE*: No more runny noses or hopeless cases. No more nickle and dime care that drains you of time and energy. No more lengthy forms and red tape. Your patients are healthy. They come to you because they want to, and they pay their own way.

• *GREAT MONEY*: 2 patients a week (and you should average more) can bring you NET PROFITS of more than $200,000.00 per year. That's after all expenses, including marketing! The recommended price is $3500 per treatment.

• *GREAT HOURS*: Exodermology requires only about 45 minutes per patient for the actual treatment, and 10 minutes per day for typical follow-up care.

In fact, Exodermology takes so little time that you can add HUNDREDS OF THOUSANDS OF DOLLARS to your bottom line without giving up any part of your present practice - until or unless you want to.

INTERNATIONAL EXODERMOLOGY SYSTEMS TRAINING COURSE INCLUDES:

• **VHS TRAINING CASSETTE** - A complete step-by-step, day-by-day instructions with latest techniques of how to perform the treatment.

• **THE PROVEN CHEMICAL FORMULA** - Including how to prepare and where to purchase ingredients.

• **PHYSICIAN'S TRAINING MANUAL** providing:
Guidelines in making patient selections
Necessary medical supplies
Pre-op and post-op instructions
Techniques and application of the treatment
Possible complications and how to handle them.

• **SCIENCE OF EXODERMOLOGY** - 23 year study establishing the benefits of the treatment.

• **UNDERSTANDING EXODERMOLOGY** - In-depth scientific explanation of the aging skin and the effects of Exodermology.

6700 W. CENTRAL, SUITE 100, WICHITA, KANSAS 67212 • (316) 942-7100

PRO - FORMA

Note: The following Pro-Forma is based on your performing EXODERMOLOGY in your existing practice.. Fixed current expenses.. rent.. phones.. payroll.. are NOT figured in the following.....

CASH FLOW PROJECTIONS

FOR EXODERMOLOGY TREATMENTS

INCOME[1]	$10,500	$17,500	$24,500	$31,500	$35,000	$35,000
Number of Treatments	(3)	(5)	(7)	(9)	(10)	(10)
Monthly Income	$10,500	$17,500	$24,500	$31,500	$35,000	$35,000
EXPENSES						
Recuperation Facility[2]	$1,440	$2,400	$3,360	$4,320	$4,800	$4,800
Medical Supplies[3]	450	750	1,050	1,330	1,500	1,500
Advertising:Newspaper	2,500	2,500	2,500	2,500	2,500	2,500
Printing/Postage	500	500	500	500	500	500
Miscellaneous	1,000	1,000	1,000	1,000	1,000	1,000
Expense Total	$5,890	$7,150	$8,410	$9,650	$10,300	$10,300
NET PROFITS	$4,610	$10,350	$16,090	$21,850	$24,700	$24,700

Total Net Profit for First Six Month Period: $ 102,360.00

First Year Proposed Net Profit: $ 250,560.00

1 Gross dollar volume @ $3,500 per treatment.
2 Based on $480 for eight day stay by each patient. (Based on a nursing home cost of $60 per day. Cost may vary depending on area.)
3 Based on $150 per patient.

MARKETING PROGRAM Including:

1. Methods of advertising - complete with 6 different proven ad layouts.

2. Receptionists Training Manual - teaching your receptionists how to handle inquiries and booking maximum number of consultations.

3. Consultants Training Manual - step-by-step guide on how to handle a consultation, handle questions asked, overcome objections and arranging details of treatment.

4. Methods of acquiring new patients.

5. Forms and records - All necessary forms and records you will require so that you can begin immediately.

6. Brochure Layout - "Camera-ready copy" for the printing of a patient information brochure to send to present and prospective patients.

7. Before and after photograph album - unretouched photos excitingly demonstrate the miraculous results of EXODERMOLOGY. (This marketing tool alone would require years and tens of thousands of dollars to put together if one were to start from scracth.

8. ALSO AVAILABLE: Membership in Exodermology Society. COMPLETE WITH Board Certification, Physicians "Hot Line", Hands-on training, Yearly Seminars, Quarterly Up-date Newsletter.

IN OTHER WORDS, WE ARE PROVIDING YOU WITH NOT ONLY THE LATEST PROCEDURES, TECHNIQUES AND FORMULAS, BUT PROVEN MARKETING TOOLS THAT CAN PROVIDE YOU WITH $200,000 TO $400,000 PER YEAR ADDITIONAL INCOME.

YOUR INTERNATIONAL EXODERMOLOGY TRAINING COURSE INCLUDES:

EIGHT DAYS OF HANDS-ON TRAINING - Conferences and seminars with IES physicians and staff.

TWO COMPLETE FACIAL TREATMENTS - for patients from your own area. (A physician may pay for his course by selling two or three treatments in his area and bring these patients with him for his training.)

VHS TRAINING CASSETTE - A complete step-by-step, day-by-day instruction with the latest techniques of how to perform the treatment.

PHYSICIANS TRAINING MANUAL - Providing:
Guidelines in making patient selections
Necessary medical supplies
Pre-op and Post-op instructions
Techniques and application of the treatment
Possible complications and how to handle them

SCIENCE OF EXODERMOLOGY - 23 year study establishing the benefits of the treatment.

UNDERSTANDING EXODERMOLOGY - In-depth scientific explanation of the aging skin and the effects of Exodermology.

MARKETING PROGRAM - Including:
Methods of advertising _ complete with 6 different ad layouts
Receptionist training manual - teaching your receptionist how to handle inquiries and booking maximum number of consulations.
Consultant training maunal - a step-by-step guide on how to handle a consultation, questions asked, overcome objections and arranging details of the treatment
Forms and Records - All necessary forms and records you will require so that you may begin immediately
Brochure Layout - "Camera ready copy" for printing of a patient information brochure to send to present and prospective patients
Before and After Photograph Album - Unretouched photos excitingly demonstrate the miraculous results of Exodermology. (This marketing tool alone would require tens of thousands of dollars to put together.)

IN OTHER WORDS, WE ARE PROVIDING YOU NOT ONLY WITH ACTUAL HANDS-ON TRAINING, THE LATEST PROCEDURES, TECHNIQUES AND FORMULAS, MANUALS AND VIDEO FOR FUTURE REFERENCE, BUT PROVEN MARKETING TOOLS THAT CAN PROVIDE YOU WITH A REWARDING ADDITIONAL INCOME.

AND IT'S TAX DEDUCTIBLE

BEFORE

MIRACLES...

IN JUST 8 DAYS...

(all photos in this brochure are unretouched)

ARE OUR STOCK IN TRADE

BEFORE

AFTER

BEFORE

AFTER

BEFORE

AFTER

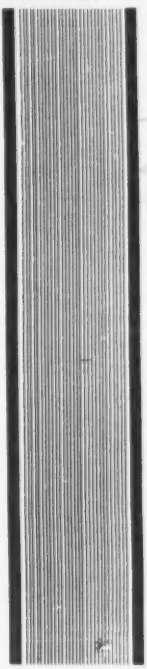
BEFORE

AFTER

Questions And Answers About Exodermology

WHAT IS EXODERMOLOGY?
Exodermology is a recognized medical procedure. The effect is similar to a face-lift, but no surgery is required.

WHAT CAN EXODERMOLOGY DO?
Just look at these unretouched photos! In person and on video-tape, the results are even more astonishing! We invite you to see for yourself.



HOW DOES EXODERMOLOGY WORK?
Aging tends to break down the polymeric bonding that gives young skin its fresh smooth appearance. As skin area begins to exceed face area, bags, folds, and wrinkles increase. Exodermology chemically dissolves the outer four layers of the skin (epidermis), and removes them as a liquid plasma. The underlying skin (dermis) shrinks, much like a sweater which has been washed. The outer layers of skin then form again over the new, wrinkle-free template of dermis. Most freckles and blemishes are eliminated by this process.

HOW LONG DOES A TREATMENT TAKE?
About a week.

IS EXODERMOLOGY PAINFUL?
There can be some discomfort during the first 4 to 6 hours similar to that of sunburn. An analgesic is usually given to relieve any such discomfort.

HOW LONG DOES A TREATMENT USUALLY LAST?
Forever. After Exodermology, the face continues to age at its normal rate. So if you look 20 years younger than your actual age when you are 50, for instance, you will still look twenty years younger when you are 70.

DOES EXODERMOLOGY WORK AS WELL AS A FACE-LIFT?
Often Much better! Exodermology achieves the same tightening and lifting effects — but unlike a surgical face-lift, Exodermology can remove wrinkles, blemishes, freckles, and acne scars; promote a fresh-looking regenerated complexion; remove flute lines around the mouth and frown lines in the T-zone of the face — all without surgical scarring, and usually at a lower cost! Just look again at these unretouched photos.

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